INTUITIVE SURGICAL INC
Form 10-K
February 01, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2010

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-30713

INTUITIVE SURGICAL, INC.

(Exact name of Registrant as Specified in its Charter)

DELAWARE	77-0416458
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

1266 KIFER RD

SUNNYVALE, CA 94086

(Address of Principal Executive Offices) (Zip Code)

(408) 523-2100

(Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Name of Each Exchange on which Registered
Common Stock, par value $0.001 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting Company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2010, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately $11,157,929,000. Shares of voting stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant s common stock on January 20, 2011 was 38,866,512.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to the definitive proxy statement for the Company s Annual Meeting of Stockholders to be held on or about April 21, 2011, to be filed within 120 days of the registrant s fiscal year ended December 31, 2010.

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FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as projects, believes, anticipates, plans, expects, intends, may, will, could, should, would, and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, procedures and procedure adoption, results of operations, future financial position, our ability to increase our revenues, the mix of our revenues between product and service revenues, our financing plans and capital requirements, our costs of revenue, our expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, cash flows and our ability to finance operations from cash flows and similar matters and include statements based on current expectations, estimates, forecasts and projections about the economies and markets in which we operate and our beliefs and assumptions regarding these economies and markets. These forward-looking statements should be considered in light of various important factors, including the following: the impact of the global and regional economic conditions and related credit markets and related impact on health care spending; health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device revenues; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which Intuitive Surgical operates; unanticipated manufacturing disruptions; delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; the results of the year-end audit and other risk factors. Readers are cautioned that these forward-looking statements are based on current expectation and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described throughout this filing and particularly in Part I, Item 1A: Risk Factors . Our actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

PART I

ITEM 1. BUSINESS

COMPANY BACKGROUND

Intuitive Surgical, Inc. was founded in 1995. We are a Delaware corporation with our corporate headquarters located at 1266 Kifer Road, Sunnyvale, California 94086. Our telephone number is (408) 523-2100, and our website address is *www.intuitivesurgical.com* . In this report, Intuitive Surgical, Intuitive, the Company, we, us, and our refer to Intuitive Surgical, Inc. and its wholly-owned subsidiaries. *Intuitive Surgical®, da Vinci®, da Vinci S®, da Vinci® S HD Surgical System , da Vinci® Si , da Vinci® Si-e HD Surgical System , EndoWrist®, Single-Site*, *DVSTAT*, and *InSite®* are trademarks of Intuitive Surgical, Inc.

We design, manufacture and market da Vinci Surgical Systems, which are advanced surgical systems that we believe represent a new generation of surgery. We believe that this new generation of surgery, which we call *da Vinci* surgery, is a significant advancement similar in scope to previous generations of surgery open surgery and minimally invasive surgery, or conventional MIS. The *da Vinci* Surgical System consists of a surgeon s console, or consoles, a patient-side cart and a high performance vision system. The *da Vinci* Surgical System translates the surgeon s natural hand movements, which are performed on instrument controls at a console, into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports. We believe that the *da Vinci* Surgical System provides the surgeon with intuitive control, range of motion, fine tissue manipulation capability and high definition 3-D vision, while simultaneously allowing the surgeons to work through the small ports of MIS.

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By placing computer-enhanced technology between the surgeon and the patient, we believe that the *da Vinci* Surgical System enables surgeons to deliver higher value minimally invasive surgical procedures to their patients. We model patient value as equal to: *procedure efficacy / invasiveness*. Here *procedure efficacy* is a measure of the success of the surgery in resolving the underlying disease and *invasiveness* is how disruptive and painful the treatment is itself. When the patient value of robotic surgery is significantly higher than competing treatment options, we have seen that patients will seek out surgeons and hospitals that offer *da Vinci* procedures, potentially resulting in a local shift of treatment approach and market share. The combination of these local adoptions can drive a disruptive change in the marketplace and can lead to the broad adoption of robotic surgery. These adoptions occur procedure by procedure, and are driven by the relative patient value of *da Vinci* procedures against alternatives for the same disease state.

The *da Vinci* Surgical System is used to perform surgery across multiple surgical specialties, including urology, gynecology, cardiothoracic surgery, transoral surgery, and general surgery.

In March 1997, surgeons using an early prototype of our technology performed the first *da Vinci* surgery on humans. In the second quarter of 1999, we began selling *da Vinci* products and services outside the United States. In July 2000, we obtained clearance from the U.S. Food and Drug Administration (FDA) to market our products in the United States for use in general laparoscopic procedures.

The following is a chronological summary of our FDA clearances to date:

July 2000 General laparoscopic procedures

March 2001 Non-cardiac thoracoscopic procedures

May 2001 Prostatectomy procedures

November 2002 Cardiotomy procedures

July 2004 Cardiac revascularization procedures

March 2005 Urologic surgical procedures

April 2005 Gynecologic surgical procedures

June 2005 Pediatric surgical procedures

December 2009 Transoral Otolaryngologic surgical procedures

In March 2008 we received clearance in the United States to market our system-held cardiac stabilizer and permission to remove the warning in our labeling regarding system use in non-arrested heart procedures. During first quarter of 2009, we received clearance to market our *da Vinci Si* Surgical System in the United States and Europe.

In November 2009, we received regulatory (Shonin) approval from the Japanese Ministry of Health, Labor, and Welfare (MHLW) for our *da Vinci S* System in Japan. During the year ended December 31, 2010, we sold 13 *da Vinci S* Systems in Japan. These sales were primarily made to early adopters. We are currently focusing our efforts with Johnson & Johnson K.K. Medical Company (Japan) on obtaining specific reimbursement approvals for *da Vinci* procedures in Japan. If we are not successful in obtaining system wide single procedure reimbursements

or obtaining approvals for future products and procedures, then the demand for our products could be limited. We have partnered with the experienced regulatory team from Johnson & Johnson K.K. Medical Company (Japan) in our Japanese regulatory process and are continuing to work with them to meet government requirements. We have partnered with Adachi Co., LTD as our separate independent distribution partner in Japan who is responsible for marketing, selling, and servicing our products in Japan.

As of December 31, 2010, we had an installed base of 1,752 *da Vinci* Surgical Systems. During the year ended December 31, 2010, we estimate that surgeons using our technology completed approximately 278,000

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surgical procedures of various types in major hospitals throughout the world. Out of those *da Vinci* procedures performed in 2010, we estimate that approximately 110,000 were *da Vinci* Hysterectomy (dVH) procedures and approximately 98,000 were *da Vinci* Prostatectomy (dVP) procedures.

We operate our business as one segment as defined by generally accepted accounting principles. Our financial results for the three years ended December 31, 2010 are discussed in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data of this Annual Report.

da Vinci Surgery

Open surgery remains the predominant form of surgery and is still used in almost every area of the body. However, the large incisions required for open surgery create trauma to the patient, resulting in longer hospitalization and recovery times, increased hospitalization costs, and additional pain and suffering. Over the past two decades, MIS has reduced trauma to the patient by allowing selected surgeries to be performed through small ports rather than large incisions, often resulting in shorter recovery times, fewer complications and reduced hospitalization costs. MIS has been widely adopted for certain surgical procedures, but it has not been widely adopted within complex surgical procedures.

The *da Vinci* Surgical System enables surgeons to overcome many of the shortcomings of both open surgery and conventional MIS and enables a new generation of surgery, *da Vinci* Surgery. Surgeons operate while seated comfortably at a console viewing a high resolution, 3-D HD image of the surgical field. This immersive visualization connects the surgeon to the surgical field and the instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, just as he or she has been trained to do in open surgery. Our technology is designed to provide surgeons with a range of motion in the surgical field analogous to the motions of a human wrist, while filtering out the tremor inherent in a surgeon s hand. In designing our products, we have focused on making our technology as simple as possible to use.

Our products are designed to convert a broad range of open surgical and conventional MIS procedures to *da Vinci* surgery. The *da Vinci* Surgical System is designed to enable surgeons to improve surgical outcomes while providing patients with the benefits of MIS. We believe that these advantages have begun to facilitate a fundamental change in surgery and that our technology overcomes many of the limitations of existing MIS tools and techniques in the following ways:

Immersive 3-D Visualization. Our vision system includes a 3-D endoscope with two independent vision channels linked to two separate color monitors. Our vision system is designed to give surgeons the perception that their hands are immersed in the surgical field even though they are outside the patient s body. As a result, we believe that surgeons no longer feel disconnected from the surgical field and the instruments, as they currently do with conventional MIS. In addition, the *3-D High Definition* vision system with advanced image processing including edge enhancement and noise reduction provides a brighter and sharper image than any other 3-D endoscope vision system currently available. The *da Vinci* Surgical System provides visualization of the target anatomy with natural depth-of-field, enhanced contrast and magnification for more accurate tissue identification and tissue layer differentiation. Improved visualization also enables surgeons to perform delicate tissue handling and dissection with added precision even in confined spaces. This precision may help the surgeon avoid trauma to surrounding structures and tissues such as the neurovascular bundle located near the prostate.

Precise and Tremor-free Endoscope Control. The *InSite* system also incorporates our proprietary *Navigator* camera control technology that allows the surgeon to easily change, move, zoom and rotate his or her field of vision. Endoscope control, provided through the hand controls and foot pedals, provides near-seamless transition between views. Surgeons can reposition the surgical camera in an instant with foot controls or zoom in, out, up, down, left and right by moving their hands in the desired direction while maintaining a stable image. Repositioning of the surgeon s head at the console does not affect image quality as with other 3-D display systems. The combination of these features offers what we believe is the most advanced surgical vision system available today.

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Intuitive Instrument Movements. Our technology is designed to directly transform the surgeon s natural hand movements outside the body into corresponding micro-movements inside the patient s body. For example, with the *da Vinci* Surgical System, a hand movement to the right outside the body causes the instrument inside the patient to be moved to the right. In contrast, conventional MIS instruments are essentially long rigid levers that rotate around a fulcrum, or pivot point, located at the port created in the body wall. In conventional MIS, the instrument tip moves in the opposite direction from the surgeon s hand and surgeons must adjust their hand-eye coordination to translate their hand movements in this backward environment.

EndoWrist Instruments Provide Natural Dexterity and Range of Motion. Our technology is designed to provide surgeons with a range of motion in the surgical field analogous to the motions of a human hand and wrist and enable more widespread use of advanced techniques as well as a reduced learning curve when compared to conventional MIS techniques. The surgeon controls the instrument movements from the surgeon s console using natural hand and wrist movements. Our proprietary instruments, which we call *EndoWrist* instruments, incorporate wrist joints that enable surgeons to reach behind tissues and suture with precision, just as they can in open surgery. Added instrument range-of-motion enhances access and safety while operating in the confined space of the closed chest, abdomen or pelvis. *EndoWrist* joints are located near the tips of all of our instruments. Conventional MIS instruments provide surgeons less flexibility, dexterity and range of motion than their own hands provide in open surgical procedures. For example, conventional MIS instruments in widespread use today do not have joints near their tips, and cannot replicate a surgeon s hand and wrist movements to perform manipulations, such as reaching behind tissue, suturing and fine dissection.

More Precise, Tremor-reduced Movement. With our technology, the surgeon can also use motion scaling, a feature that translates, for example, a three-millimeter hand movement outside the patient s body into a one-millimeter instrument movement in the surgical field inside the patient s body. Motion scaling is designed to allow greater precision than is normally achievable in either open surgery or conventional MIS. In addition, our technology provides the filtering of tremor inherent in a surgeon s hands.

Superior Surgeon Ergonomics. The *da Vinci* Surgical System is designed to allow surgeons to operate while seated, which is not only more comfortable, but also may be clinically advantageous due to reduced surgeon fatigue. The *da Vinci* Surgical System s design provides natural hand to eye alignment at the surgeon s console, which provides improved ergonomics over traditional laparoscopic technology. Since the *da Vinci* Surgical System s robotic arms hold the camera and instruments steady, there is less surgeon assistance required and reduced surgeon fatigue and also potentially reduced abdominal wall torque.

Improved Ease-of-Use shortens learning curves. We have designed our products to make them as simple as possible to use, even though the underlying technology is inherently complex. We believe that tissue manipulations using our products are as natural as hand movements in open surgery. In our experience, based on feedback from surgeons who have performed thousands of procedures, surgeons can learn to manipulate our instruments with less training than is typically required for the surgeon to become skilled in conventional MIS. The time required to learn to perform surgical procedures using the *da Vinci* Surgical System varies depending on the complexity of the procedure and the surgical team s experience with MIS techniques.

Multi-Specialty Surgical Platform. The *da Vinci* Surgical System is designed to enable surgeons to perform a wide range of surgical procedures. To date, we believe surgeons have used the *da Vinci* Surgical System to perform nearly 100 different types of surgical procedures.

We believe that these technological advantages provide the patient with benefits of reduced trauma while restoring to the surgeon the 3D visualization, range of motion and fine tissue control consistent with open surgery. We believe that our technology has the potential to change surgical procedures in two basic ways:

Convert a Large Percentage of Open Procedures to da Vinci Surgery. We believe that our technology has the potential to convert a large percentage of open procedures which are traditionally performed through large incisions to *da Vinci* surgery.

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Facilitate Difficult MIS Operations. We believe that several surgical procedures that are performed only rarely today using conventional MIS techniques can be performed routinely using *da Vinci* surgery. Some procedures have been adapted for MIS techniques but are extremely difficult and are currently performed by a limited number of highly skilled surgeons. We believe our *da Vinci* Surgical System will enable more surgeons at more institutions to perform these procedures.

Intuitive Surgical s Products

Using the da Vinci Surgical System

During a procedure, the patient-side cart is positioned next to the operating table with the electromechanical arms arranged to provide access to the initial ports selected by the surgeon. Once the ports have been placed by the surgeon, the arms of the *da Vinci* Surgical System are positioned and the *EndoWrist* instruments are introduced into the patient s body. The surgeon then performs the procedure while sitting comfortably at the surgeon s console, manipulating the instrument controls and viewing the operation through our high performance 3-D vision system. When a surgeon needs to change an instrument, as is done many times during an operation, the instrument is withdrawn from the surgical field using the controls at the console, in similar fashion to the way a surgeon withdraws instruments from the patient in conventional MIS. A scrub nurse standing near the patient removes the instrument from the electromechanical arm and replaces it with another instrument, in a process designed to be rapid enough not to disturb the natural flow of the procedure. As a result, the scrub nurse plays a role similar to that played in open surgery and conventional MIS. At the conclusion of the operation, the small port incisions are closed with either suture or band-aids.

Our principal products include three models of *da Vinci* Surgical System *da Vinci Si* Surgical System, *da Vinci S* Surgical System and standard *da Vinci* Surgical System, along with a variety of *EndoWrist* instruments and accessories.

da Vinci Surgical System

Our *da Vinci* Surgical System is comprised of the following components:

Surgeon s Console or Consoles. The *da Vinci* Surgical System allows one or two surgeons to operate while comfortably seated at an ergonomic console viewing a 3-D image of the surgical field. The surgeon s fingers grasp the instrument controls below the display with hands naturally positioned relative to his or her eyes. Using electronic hardware, software, algorithms, mechanics and optics, our technology translates the surgeon s hand movements into precise and corresponding real-time micro movements of the *EndoWrist* instruments positioned inside the patient.

Patient-Side Cart. The patient-side cart, which can be easily moved next to the operating table, holds electromechanical arms that manipulate the instruments inside the patient. Up to four arms attached to the cart can be easily positioned as appropriate, and then locked into place. The first two arms, one representing the left hand and one representing the right hand of the surgeon, hold our *EndoWrist* instruments. The third arm positions the endoscope, allowing the surgeon to easily move, zoom and rotate his or her field of vision. The fourth arm provides additional surgical capabilities by holding an additional *EndoWrist* instrument as well as potentially reducing the need for an assistant surgeon. The surgeon has a choice of simultaneously controlling any two of the operating arms by tapping a foot pedal underneath the surgeon s console. The fourth instrument arm extends surgical capabilities by enabling the surgeon to add a third *EndoWrist* instrument and perform additional tasks such as applying counter traction and following running sutures. The fourth instrument arm is a standard integrated feature on the *da Vinci Si* and *da Vinci S* surgical systems and is available as a field upgrade on three-arm standard *da Vinci* and three-arm *da Vinci S* Surgical Systems.

3-D Vision System. Our vision system includes our *InSite* 3-D endoscope with two separate vision channels linked to two separate color monitors through high performance video cameras and specialized edge enhancement and noise reduction equipment. The resulting 3-D image has high

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resolution and contrast and no flicker or cross fading, which sometimes occurs in single monitor systems, and minimizes eye fatigue. Our HD vision system provides at least 20% more viewing area and enhances visualization of tissue planes and critical anatomy compared with our standard vision system. The digital zoom feature in the 3-D HD vision system allows surgeons to magnify the surgical field of view without adjusting endoscope position and reduces interference between the endoscope and instruments. The 3-D HD vision is a standard integrated feature on *da Vinci S* Surgical Systems sold today and as an upgrade option to our existing customers who own a *da Vinci S* Surgical System without HD vision.

Our newest *da Vinci* model, the *da Vinci Si*, was launched in April 2009. The *da Vinci Si* System retains and builds on the core technology at the heart of the existing *da Vinci* and *da Vinci S* Systems. The *da Vinci Si* brings to market three significant innovations.

First, our *InSite* imaging system has been substantially redesigned for increased visual acuity and improved ease-of-use. The HD imaging system s increased performance is similar to the move from 720p to 1080i in commercial television. We believe that the increased visual performance will continue to enhance surgeon precision and confidence, which may contribute to improved patient outcomes and shorter procedure times. Additionally, the *da Vinci Si* surgeon s user interface has been redesigned to allow simplified and integrated control of the *da Vinci* Surical System including the ability to set and recall individual surgeon preferred ergonomic and visualization settings. We believe the simplified interface may allow for easier surgeon training. The third significant enhancement is the introduction of a second surgeon s console, which we envision to be used in two possible ways: to provide assistance to the primary surgeon during surgery, or, to be used as an active aid during surgeon-student training sessions. With the *da Vinci Si*, a surgeon sitting at a second console can view the same surgery as the primary surgeon and can be passed control of some or all of the *da Vinci* instruments during a case. In addition, the surgeons can control 3D virtual pointers to augment the dual surgeon experience. We believe the dual console configuration could both shorten the learning curve for new surgeons and will allow for collaborative surgery in complex cases.

In the third quarter of 2010, we introduced the new *Si-e* model of the *da Vinci* Surgical System. The 3-arm *Si-e* System is designed to deliver core *da Vinci* functionality, providing a flexible, capable and economical solution for many robotic-assisted procedures. The *da Vinci Si-e* system is fully upgradeable to the *da Vinci Si* model by adding a fourth arm (third instrument arm), and other enhancements. During the year ended December 31, 2010, we sold 9 *da Vinci Si-e* systems.

In the fourth quarter of 2010, we introduced the *da Vinci* Skills Simulator. The simulator is a practice tool which will begin shipping in early 2011 for the *da Vinci* Si Surgical System that gives a user the opportunity to practice his or her facility with the surgeon console controls. The simulator incorporates three-dimensional, physics-based computer simulation technology to immerse the user within a virtual environment. The user navigates through the environment and completes exercises by controlling virtual instruments from the surgeon console. The suite of exercises includes novice, intermediate, and advanced levels. Upon completion of a skills exercise, the simulator provides a quantitative assessment of user performance based on a variety of task-specific metrics. The Skills Simulator is intended to augment, not replace, existing training programs for the *da Vinci* Si Surgical System.

EndoWrist Instruments, Accessories and Vision Components

We manufacture a variety of *EndoWrist* instruments, each of which incorporates wrist joints for natural dexterity, with tips customized for various surgical procedures. *EndoWrist* instruments are offered in both 5mm and 8mm diameter sizes. The instruments mount onto the electromechanical arms that represent the surgeon s left and right hands and provide the mechanical capability necessary for performing complex tissue manipulations through ports. At their tips, the various *EndoWrist* instruments include forceps, scissors, electrocautery, scalpels and other surgical tools that are familiar to the surgeon from open surgery and

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conventional MIS. Generally, a variety of *EndoWrist* instruments are selected and used interchangeably during a surgery. Where instrument tips need to incorporate a disposable component, such as scalpel blades, we sell disposable inserts. We plan to continue to add new types of *EndoWrist* instruments for additional types of surgical procedures.

The *EndoWrist* instruments are sterilizable and most are reusable for a defined number of procedures. A programmed memory chip inside each instrument performs several functions that help determine how the system and instruments work together. When an *EndoWrist* instrument is attached to an arm of the patient-side cart, the chip performs an electronic handshake that ensures the instrument was manufactured by us and communicates the type and function of the instrument and number of past uses. For example, the chip distinguishes between scissors and a scalpel and controls the unique functions of different instruments as appropriate. In addition, the chip will not allow the instrument to be used for more than the prescribed number of procedures so that its performance meets specifications during each procedure.

We also sell various vision and accessory products, which are used in conjunction with the *da Vinci* Surgical System as surgical procedures are performed. Accessory products include sterile drapes used to ensure a sterile field during surgery, vision products such as replacement 3-D stereo endoscopes, camera heads, light guides, and other miscellaneous items. Existing *da Vinci S* instruments and most *da Vinci S* accessories are compatible with the *da Vinci Si* system.

Our Objective

Our objective is to bring the benefits of minimally invasive surgery to as many patients as possible. Our priorities to accomplish this are as follows:

1. *Patient Value.* We believe that the value of a surgical procedure to a patient can be defined as: Patient Value = Efficacy/Invasiveness. Most patients will place higher value on procedures that are not only more efficacious, but also less invasive than alternative treatments. Our goal is to provide patients with procedure options that are both highly effective and less invasive than other surgical options.

2. *Key Procedures.* We believe that the adoption of *da Vinci* surgery occurs based upon the patient value it brings to each surgical procedure. We therefore focus our development efforts on those procedures to which we believe our products bring the highest patient value. We currently focus on five surgical specialties: urologic surgery, gynecologic surgery, cardiothoracic surgery, general surgery and head and neck surgery. In 2010, the mix of procedures performed with the *da Vinci* Surgical System among these five surgical specialties was largest within gynecology, followed by urology, cardiothoracic, general surgery and head and neck surgery. The *da Vinci* Surgical System is used to perform, among other procedures, *da Vinci* Prostatectomy, *da Vinci* Partial Nephrectomy & Nephrectomy, *da Vinci* Cystectomy, *da Vinci* Pyeloplasty, *da Vinci* Hysterectomy, *da Vinci* Myomectomy, *da Vinci* Sacral Colpopexy, *da Vinci* Mitral Valve Repair, *da Vinci* Revascularization, *da Vinci* Thoracoscopy, *da Vinci* Lobectomy, *da Vinci* Gastric Bypass, *da Vinci* Low Anterior Colon Resection, *da Vinci* Thyroidectomy and *da Vinci* Trans Oral Robotic Surgery (for cancers of the throat). The development of new specialties and key procedures in partnership with leading surgeons have been, and will continue to be, a catalyst for the growth of our company.

3. *Surgeon Value.* We train and assist surgeons in building their practices by delivering superior patient value through improved surgical efficacy and reduced surgical trauma.

4. *Hospital Value.* We assist both academic and community hospitals in building value by offering superior patient value in terms of improved surgical efficacy and reduced surgical trauma thereby increasing surgical revenue and reducing costs through lower complication rates and reduced length of patient stay. We expect these efforts to increase demand for our products among competitive hospitals, surgeons and referring physicians.

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Clinical Applications

We believe our technology is capable of enhancing or enabling a wide variety of procedures in many surgical specialties. Surgeons using our *da Vinci* Surgical System have completed hundreds of thousands of surgical procedures of various types, including urologic, gynecologic, cardiothoracic, general and head and neck surgery procedures. These surgical applications, which are currently cleared by the FDA, are further described below.

Urologic Surgery

Prostatectomy. Radical prostatectomy is the removal of the prostate gland in patients diagnosed with clinically localized prostatic cancer. The standard approach to removal of the prostate has been via an open surgical procedure. The laparoscopic approach, while not prevalent, is an option, but is difficult and poses challenges to even the most skilled urologist. The *da Vinci* Surgical System allows for improved visualization of the gross anatomy (dorsal veins, endopelvic fascia, bladder muscle, puboprostatic ligaments), microanatomy (bladder muscosa, nerve bundles) and tissue planes, which are critical for an anatomic dissection. Peer-reviewed clinical publications have reported that radical prostatectomy using the *da Vinci* Surgical System has improved oncologic results, reduced operative blood loss, reduced postoperative pain, improved cosmesis, quicker return to normal activity and may provide a better nerve-sparing operation. The *da Vinci* Surgical System has enabled a large number of surgeons to convert from using an open surgical technique to a minimally invasive technique.

Nephrectomy (partial and total). Partial nephrectomy is the removal of a small portion of a kidney (typically, an area of the kidney containing a tumor), and total nephrectomy is the total removal of a kidney. Partial nephrectomies are most commonly performed in patients diagnosed with clinically localized renal cancer, when the tumor size is four centimeters or less in size. Total nephrectomies are also most commonly performed in patients diagnosed with clinically localized renal cancer that are not resectable with a partial nephrectomy and are also performed in patients suffering from various benign conditions. There are currently three surgical approaches to performing partial nephrectomies: open surgical technique, which requires a large incision; laparoscopy, which allows the surgeon to operate through several small incisions, and hand assisted, which incorporates both laparoscopy and a modified open surgical technique. Surgeons have reported that the combination of the *da Vinci* Surgical System s improved visualization capabilities and enhanced dexterity allows for greater precision and control during these complex surgical procedures, which could enable a large number of these procedures to be performed through this minimally invasive technique resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Cystectomy. Cystectomy is the removal of the bladder in patients diagnosed with bladder cancer. The current standard approach to the removal of the bladder is via an open surgical procedure. The laparoscopic approach, while not prevalent, is an option, but is difficult and poses challenges to even the most skilled urologist. The *da Vinci* Surgical System allows for improved visualization of the gross anatomy and tissue planes, which are critical for an anatomic dissection. The *da Vinci* Surgical System has enabled a number of these procedures to be converted from an open surgical technique to a minimally invasive technique, thus reducing blood loss and pain and allowing for the patient s quicker return to normal activity.

Pyeloplasty. Pyeloplasty is the surgical reconstruction or revision of the renal pelvis to drain and decompress the kidney. In nearly all cases, the goal of pyeloplasty surgery is to relieve a uretero-pelvic junction (UPJ) obstruction. There are currently two surgical approaches to performing pyeloplasties: open surgical technique, which requires a large incision, and laparoscopy, which allows the surgeon to operate through several small incisions. Surgeons have reported that the combination of the *da Vinci* Surgical System s improved visualization capabilities and enhanced dexterity allows for greater precision and control during these complex surgical procedures, which could enable a large number of these procedures to be performed through this minimally invasive technique resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

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Gynecologic Surgery

Hysterectomy. Removal of the uterus is one of the most commonly performed surgeries in gynecology and is performed for a variety of benign and malignant conditions. Hysterectomies can be performed using open surgery, a vaginal approach, or MIS techniques, which include both laparoscopic and robotic approaches. Performing a hysterectomy requires a significant degree of tissue manipulation in the dissection and ligation, or tying, of blood vessels, ligaments and other pelvic structures. An MIS approach to hysterectomy is associated with less pain, shorter hospital stay and quicker recovery compared to an open surgical technique. It is often difficult to ensure the identification and prevention of injury to the ureters and bladder with conventional laparoscopic instruments because of the limited angles at which these instruments can be positioned. Furthermore, in hysterectomy procedures for treating endometrial or cervical cancer, it is difficult to access and remove a large number of lymph nodes to better stage the cancer with conventional laparoscopic techniques. A robotic technique with use of the *da Vinci* Surgical System can bring the benefits of MIS to the patients while offsetting the limitations of conventional laparoscopy. Specifically, patients that would traditionally have a hysterectomy through an open surgical technique, for a complex-benign or a malignant clinical condition may see significant benefit from a robotic MIS approach including reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis. We believe that our products will increase the surgeon s dexterity in this procedure and, as a result, may have a significant impact on safety, operating time, and rate of adoption of port-based techniques in hysterectomy.

Myomectomy. Myomectomy, or removal of a myoma/fibroid, is a surgical procedure performed when uterine preservation is sought. Women who desire to remain fertile are candidates for this procedure. Due to the substantial suturing required for this procedure, the standard surgical approach remains an open incision. There are some highly skilled gynecological laparoscopists who perform laparoscopic myomectomies, but to this point, it has remained a small minority. We believe that the *da Vinci* Surgical System s improved visualization capabilities and enhanced dexterity allows for greater precision and control during these complex surgical procedures, which could enable a large number of these procedures to be performed minimally invasively resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Sacral Colpopexy. The abdominal sacral colpopexy is one of the most successful operations for vaginal vault prolapse. Sacral colpopexy involves suturing a synthetic mesh that connects and supports the vagina to the sacrum (tailbone). A sacral colpopexy can be performed using conventional laparoscopic technique, it is however, generally described as difficult and cumbersome to perform. *da Vinci* sacral colpopexy combines the benefits of a minimally invasive procedure with the durability of a traditional abdominal approach resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Cardiothoracic Surgery

Mitral Valve Repair. When patients are diagnosed with mitral valve disease, there are two surgical treatment options from which they can choose: mitral valve replacement or mitral valve repair. Mitral valve repairs are generally preferred over mitral valve replacement for a number of reasons, which include longevity and durability of the repaired valve over a replacement valve and the elimination or reduction of the patient s post-surgical pharmaceutical regimen. Since mitral valve repairs are considered to be more technically challenging than mitral valve replacements, they are only performed approximately 50% of the time. When performing *da Vinci* mitral valve repairs, surgeons have reported that the enhanced 3-D visualization provides for essential identification of difficult to see anatomical structures and tissue planes. *EndoWrist* joints permit them to precisely manipulate delicate structures inside of the heart and accurately place sutures into the targeted tissues. In addition, surgeons using the *da Vinci* Surgical System to operate from a lateral right-sided approach have reported that this requires less tissue manipulation than operating through a sternotomy, while providing greater anatomical exposure. As a result of these factors, several of our surgeon customers have reported a significant improvement in their mitral valve repair rates (>95%) over mitral valve replacements within their practices. Our

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da Vinci Surgical System is enabling heart valve repairs to be performed through small ports in a manner that could not have been accomplished with open surgery resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Cardiac Revascularization or Coronary Artery Bypass. The traditional approach to coronary artery bypass grafting, or CABG, involves splitting the breastbone via a median sternotomy incision, placing the patient on cardio pulmonary bypass, or CPB, and bypassing diseased segments of arteries in the heart with conduit arteries and veins. Over time, successful results from this operation have been widely reported. However, there are known morbidities from this approach that MIS techniques for coronary artery bypass surgery seek to overcome. With assistance from the *da Vinci* Surgical System, patients can undergo single or multi-vessel full surgical revascularization utilizing all arterial conduits (IMA/BIMA), while avoiding CPB and the median sternotomy incision, thus reducing the morbidities associated with these procedures. In Single-Vessel or Multi-Vessel Small Thoracotomy bypass, or SVST/ MVST procedures, surgeons use the *da Vinci* Surgical System to precisely mobilize one or both internal mammary arteries for use in the bypass operation. This is accomplished through three small port incisions in the left chest and once completed, the middle port incision is extended into a four- to six- centimeter incision, enabling the surgeon to complete the anastomoses directly through the incision resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis. In addition to reducing known morbidities from standard open-chest coronary artery bypass surgery, revascularization with the *da Vinci* Surgical System places the patient on an accelerated path to recovery. When combined with percutaneous coronary intervention (PCI) in a hybrid approach, *da Vinci* Revascularization may also provide better outcomes than stenting alone, resulting in higher patency and lower re-intervention rates.

Thoracic Surgery. A number of surgical procedures performed in the thorax, or chest cavity, can be accomplished by minimally invasive methods. These methods are generally referred to as video-assisted thoracoscopic (VATS) surgery. Procedures performed via these methods include wedge resection, lobectomy, thymectomy, mediastinal mass excision and esophagectomy. They include various types of lung resection, biopsy procedures, node dissections, nerve resections and esophageal surgery. Conventional thoracoscopic tools have all the limitations of conventional laparoscopic tools, such as backward counter-intuitive movement and limited range of motion. We believe that the capability of our technology to operate dexterously in the small and restrictive space of the chest cavity offers significant clinical value in the performance of advanced thoracic surgical procedures like lobectomy. Use of the *da Vinci* System allows formal, anatomical resection, along with complete mediastinal lymph node dissection the gold standard treatment for early stage non-small cell lung cancer. This approach provides effective treatment without the need for a formal thoracotomy (open technique), or facilitation-access mini-thoracotomy (video-assisted thoracic surgery or VATS technique).

General Surgery

Low Anterior Resection. Low anterior resection (LAR) is a surgical procedure to treat rectal cancer. The surgeon dissects and removes the majority of the rectum, descending colon and a portion of healthy tissue and lymph nodes. Conventional laparoscopy is not widely employed to treat rectal cancer due to the high degree of difficulty. In fact, literature suggests that laparoscopic LAR may increase the rate of surgical complications and positive oncologic margins. Furthermore, pelvic nerve bundles that enable healthy bladder and sexual function may be compromised in *both* open and laparoscopic LAR procedures due to poor exposure, visualization and dexterity inherent in operating with conventional tools in a tight and deep surgical space. In contrast, the *da Vinci* Surgical System is a proven tool for performing precise cancer operations, with minimal complications, in the deep pelvis. As with *da Vinci* Prostatectomy, *da Vinci* Low Anterior Resection provides surgeons with greater dexterity, visualization and control when performing rectal cancer surgery as compared to open and laparoscopic approaches. We believe that *da Vinci* Low Anterior Resection not only enables a more precise operation with fewer complications and shorter recovery time, but may also improve oncologic outcomes.

Gastric Bypass. A growing number of patients are undergoing surgical treatment for their morbid obesity. Laparoscopic roux-en-Y gastric bypass, or LRYGB, is the most commonly performed surgical procedure for

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morbid obesity in the United States. Briefly, the LRYGB operation promotes weight loss by two mechanisms. First, the size of the stomach is greatly reduced by surgical stapling , thus restricting the amount of food the patient can consume at a given time. Second, a long segment of intestine is bypassed causing less food to be absorbed. The LRYGB is one of the most technically challenging laparoscopic procedures because of the suturing, stapling and tissue (bowel) manipulation that is required. A critical portion of the operation is anastomosing the stomach to the small intestine. Leaks in the anastomosis are the cause of major complications that can result in death. The *da Vinci* Surgical System is used by surgeons in suturing this anastomosis. We believe procedures performed with the *da Vinci* Surgical System incorporating a double-layered hand-sewn anastomosis results in fewer anastomotic leaks than in traditional laparoscopic procedures.

Head and Neck Surgery

Transoral Surgery. Head and neck cancer, which most often occurs in the throat due to prolonged tobacco and alcohol use, and has been linked to human papilloma virus, is treated by surgical resection or chemoradiation. Surgical resection is performed most often by an open approach, which at times requires a jaw-splitting mandibulotomy. This procedure, while effective in treating cancer, is traumatic and disfiguring to the patient and requires extensive recovery and rehabilitation. Minimally invasive approaches via the mouth (transoral surgery) have seen little adoption due to a high degree of difficulty and line-of-sight limitations of conventional endoscopic tools. While chemoradiation does allow patients to avoid traumatic surgical incisions, literature suggests that this modality diminishes patients ability to speak and swallow normally. *da Vinci* Transoral Surgery, on the other hand, allows surgeons to treat cancers occurring in the oropharynx (e.g., tonsil and base of tongue) and larynx via the mouth. The *da Vinci* Surgical System extends the ability to resect tumors transorally, avoiding in many cases an open approach via mandibulotomy. We believe that *da Vinci* Transoral Surgery provides a more precise platform for complete resection of cancers of the oral cavity and maximizes the preservation of healthy tissue to maintain normal speech and swallowing function resulting in reduced length of hospital stay and time in which the patient requires a feeding tube.

Thyroidectomy. Thyroid cancer is most commonly treated by thyroidectomy, the removal of all or part of the thyroid gland. Complete resection of the cancer and surrounding gland is required for proper oncologic outcomes. The surgeon must also precisely dissect and preserve an important nerve that sits deep to the gland in order to maintain proper voice function and spare the parathyroid glands that regulate calcium levels in the blood. For these reasons, open surgery is the dominant surgical approach. Endoscopic approaches with good functional outcomes have proven too difficult for the majority of surgeons. Open surgery however leaves a prominent and unsightly neck scar often as large as four to six centimeters. Surgeons are now using the *da Vinci* Surgical System to perform thyroidectomies from a remote site in the axilla (armpit). The precision, exposure and visualization achieved with the *da Vinci* Surgical System enables an endoscopic technique that is accessible to a broader set of surgeons. With *da Vinci* Thyroidectomy, surgeons are now able to offer their patients a procedure with no neck scar while maintaining the outcomes of open surgery for cancer control, voice preservation and calcium blood levels.

Additional Clinical Applications

We believe there are numerous additional applications that can be addressed with the *da Vinci* Surgical System. Surgeons using the *da Vinci* Surgical System have performed nearly 100 different types of surgery throughout the world.

Sales and Customer Support

We market our products through a direct sales force in the United States and parts of Europe. We also market our products outside the United States through distributors. Our direct sales force is comprised of sales managers, clinical sales representatives, training specialists, and technical service representatives. Sales activities include educating surgeons and hospital staff across multiple surgical specialties on the advantages of *da Vinci*

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surgery and the clinical applications that our technology enables. We also train our sales force to educate hospital management on the potential benefits of adopting our technology, including clinical benefits of *da Vinci* Surgery, reductions in complications and length of stay and the resulting potential for increased patient satisfaction and volume. Once a hospital has installed a *da Vinci* Surgical System, our clinical sales representatives help drive the utilization of the system, and our technical service representatives provide service and maintenance for the system. No one customer accounted for more than 10% of revenue during the years ended December 31, 2010, 2009 and 2008.

As of December 31, 2010, we had approximately 700 employees in our field sales and service organizations, up from approximately 490 employees in these organizations as of December 31, 2009, primarily reflecting growth in our clinical sales force supporting procedures performed at customer sites. We expect to continue growing these organizations as we expand our business.

Our *da Vinci* Surgical System typically has a lengthy sales cycle. It is viewed as a major capital equipment purchase by our customers and sales are often affected by the timing of their budgeting cycles. Our sales of *da Vinci* Surgical Systems tends to be heaviest during the third month of each quarter. A portion of our customers acquire *da Vinci* Surgical Systems through a capital lease or operating lease with a third-party leasing company. In these instances, we typically sell the *da Vinci* System to the hospital or leasing company, and the hospital enters into an independent arrangement with the leasing company. Therefore we treat these leasing transactions the same as sales transactions for purposes of recognizing revenue for the sale. During the twelve months ended December 31, 2010, approximately 19% of our *da Vinci* System sales involved a lease.

Our sales of *EndoWrist* instruments and accessories are driven by surgical procedures performed on installed systems. Our customers place orders to replenish their supplies of *EndoWrist* instruments and accessories on a regular basis. Orders received are typically shipped within one business day. Direct customers who purchase a new *da Vinci* System typically place an initial stocking order of *EndoWrist* instruments and accessories within one month of receiving their system.

Our business is subject to seasonal fluctuations. Historically, our sales of *da Vinci* Surgical Systems have tended to be heaviest during the third month of each fiscal quarter, and lighter in the third and first fiscal quarters and heavier in the fourth fiscal quarter. In addition, historically, we have experienced lower procedure counts in the third fiscal quarter, higher procedure counts in the fourth fiscal quarter and lower procedure counts in the first fiscal quarter. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases.

Customer Support and Training Programs

Our goal is to provide exceptional value to our customers: patients, surgeons and hospitals. We have a network of field service engineers across the United States, Europe and Asia and maintain relationships with various distributors around the globe. This infrastructure of service and support specialists offer a full complement of services, including 24/7 support, installation, repair and maintenance for our customers.

We generate service revenue by providing these services to our customers through comprehensive service contracts and time and material programs.

We provide basic system training that teaches the fundamental operating principles of the *da Vinci* Surgical System to surgeons and operating room nurses. We have established training centers where initial system training and ongoing surgical procedural training are provided, the latter by expert surgeons. In addition, we facilitate the proctoring of surgeons who are new to *da Vinci* Surgery by experienced *da Vinci* System users. Proctors provide training to other surgeons on how to perform certain surgical procedures with the *da Vinci* System.

Research and Development

We focus our research and development efforts on providing our customers with new products and product improvements that enable them to perform improved and innovative surgical procedures with less difficulty. We

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maintain research and development and engineering staff responsible for product design and engineering. We invested $116.0 million, $95.1 million and $79.4 million of research and development expenses for the years ended December 31, 2010, 2009 and 2008, respectively. This investment is applied generally to all product areas, with specific areas of focus being identified from time to time.

We establish strategic alliances with other medical device companies to complement our research and development effort. To date, these alliances have taken several forms, including cooperation in the areas of product development, training, and procedure development and marketing activities. We have formed alliances with several companies, including, but not limited to, Covidien Ltd., Johns Hopkins University, Johnson & Johnson, Luna Innovations, Inc., Medtronic, Inc., Novadaq Technologies, Inc., Olympus Corporation, USGI Medical, Inc and Cardica, Inc.

Manufacturing

We manufacture our *da Vinci* Surgical Systems at our facility in Sunnyvale, California. We manufacture our *Endowrist* instruments at our Sunnyvale facility and at our Mexicali, Mexico facility. We began production in Mexicali in July 2008.

We purchase both custom and off-the-shelf components from a large number of suppliers and subject them to stringent quality specifications. Some of the components necessary for the assembly of our products are currently provided to us by sole-sourced suppliers (the only recognized supply source available to us) or single-sourced suppliers (the only approved supply source for us among other sources). We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of finished goods.

Competition

We consider our primary competition to be existing open surgery, conventional MIS, drug therapies, radiation treatment and emerging interventional surgical approaches. Our success depends on continued clinical and technical innovation, quality and reliability as well as educating hospitals, surgeons and patients on the demonstrated benefits associated with *da Vinci* surgery and its superiority to other techniques. We also face competition from several companies that are developing new approaches and products for the MIS market. While a few of these potential competitors are seeking to incorporate robotics into their product offerings, most are focused on adding capability to manual MIS systems. Because many of these developments are aimed at MIS, we believe that our *da Vinci* Surgical System may actually prove complementary to these new technologies.

In addition, a number of companies are using or planning to use robots and computers in surgery, including but not limited to Alf-X , EndoControls, Inc., Meere Company, Inc., Olympus, and Titan Medical. Any company with substantial experience in industrial robotics could potentially expand into the field of surgical robotics and become a competitor. Our revenues may be adversely impacted if our competitors develop and introduce products that compete in our markets.

Intellectual Property

We place considerable importance on obtaining and maintaining patent, copyright and trade secret protection for significant new technologies, products and processes.

We generally rely upon a combination of patents, copyrights, trademarks, trade secret and other laws (e.g., contractual restrictions on disclosure, copying and transferring title, including confidentiality agreements with vendors, strategic partners, co-developers, employees, consultants and other third parties) to protect our proprietary rights in the developments, improvements and inventions that we have originated and which are incorporated in our products or that fall within our fields of interest. We also have agreements with third parties that provide for several exclusive and non-exclusive licenses to their patents.

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As of December 31, 2010, we held ownership or exclusive field-of-use license for more than 850 U.S. and foreign patents and more than 950 U.S. and foreign patent applications.

Our patents and patent applications relate to a number of important aspects of our technology, including our surgeon s console, electromechanical arms, vision system, endoscope positioning system and *EndoWrist* instruments. We intend to continue to file additional patent applications both in the United States and in foreign jurisdictions to seek protection for our technology.

While our patents are an important element of our success, our business as a whole is not significantly dependent on any one patent. We have trademarks, both registered and unregistered, that are maintained and enforced to provide customer recognition for our products in the marketplace.

Government Regulation

United States

Our products and operations are subject to extensive and rigorous regulation by the FDA. The FDA regulates the development, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution, and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, medical devices are classified into one of three classes Class I, Class II or Class III depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Our current products are Class II medical devices.

Class II devices are those which are subject to the general controls and most require premarket demonstration of adherence to certain performance standards or other special controls, as specified by the FDA, and clearance by the FDA. Premarket review and clearance by the FDA for these devices is accomplished through the 510(k) premarket notification process. For most Class II devices, the manufacturer must submit to the FDA a premarket notification submission, demonstrating that the device is substantially equivalent in intended use and technology to a predicate device that is either:

1. a device that has grandfather marketing status because it was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or

2. a Class I or II device that has been cleared through the 510(k) process.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device. The FDA has a statutory 90-day period to respond to a 510(k) submission. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous pre-marketing requirements.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a pre-market approval application, or PMA, approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer s decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

Our manufacturing processes are required to comply with the FDA s Good Manufacturing Practice, or GMP, requirements contained in its Quality System Regulation, or QSR. The QSR covers, among other things,

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the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of a company s products. The QSR also requires maintenance of a device master record, device history record, design history file and complaint files. Compliance with the QSR is necessary to receive FDA 510(k) clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings. Among other things, these regulations require that manufacturers establish performance requirements before production. A company s facility, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Form FDA 483 reports (listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures), or W