COOPER COMPANIES INC
Form 10-K
December 20, 2013

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED OCTOBER 31, 2013
COMMISSION FILE NO. 1-8597

THE COOPER COMPANIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-2657368
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)
6140 Stoneridge Mall Road, Suite 590 Pleasanton, California	94588
(Address of principal executive offices)	(Zip Code)
(925) 460-3600	
(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, $.10 par value, and associated rights	New York Stock Exchange

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, 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 (§232.405 of this chapter) 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one).
Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

(Do not check if a 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

On November 30, 2013, there were 47,655,018 shares of the registrant's common stock held by non-affiliates with aggregate market value of $5.2 billion on April 30, 2013, the last day of the registrant's most recently completed fiscal second quarter.

Number of shares outstanding of the registrant's common stock, as of November 30, 2013: 48,000,571

Documents Incorporated by Reference:

Document	Part of Form 10-K
Portions of the Proxy Statement for the Annual Meeting of Stockholders scheduled to be held in March 2014	Part III

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

Annual Report on Form 10-K
for the Fiscal Year Ended October 31, 2013

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1934 and Section 21E of the Securities Exchange Act of 1934. These include statements relating to plans, prospects, goals, strategies, future actions, events or performance and other statements which are other than statements of historical fact. In addition, all statements regarding anticipated growth in our revenue, anticipated effects of any product recalls, anticipated market conditions, planned product launches and expected results of operations and integration of any acquisition are forward-looking. To identify these statements look for words like “believes,” “expects,” “may,” “will,” “should,” “could,” “seeks,” “intends,” “plans,” “estimates” or “anticipates” and similar words or phrases. Forwa statements necessarily depend on assumptions, data or methods that may be incorrect or imprecise and are subject to risks and uncertainties. Among the factors that could cause our actual results and future actions to differ materially from those described in forward-looking statements are:

- Adverse changes in global or regional general business, political and economic conditions due to the current global economic downturn, including the impact of continuing uncertainty and instability of certain European Union countries which could adversely affect our global markets.
- Foreign currency exchange rate and interest rate fluctuations including the risk of further declines in the value of the yen that would decrease our revenues and earnings.
- Acquisition integration delays or costs or the requirement to record significant adjustments to the preliminary fair value of assets acquired and liabilities assumed within the measurement period.
- A major disruption in the operations of our manufacturing, research and development or distribution facilities, due to technological problems, natural disasters or other causes.
- Disruptions in supplies of raw materials, particularly components used to manufacture our silicone hydrogel lenses.
- The impact of acquisitions or divestitures on revenues, earnings or margins.
- Limitations on sales following new product introductions due to poor market acceptance.
- New competitors, product innovations or technologies.
- Reduced sales, loss of customers and costs and expenses related to recalls.
- New U.S. and foreign government laws and regulations, and changes in existing laws, regulations and enforcement guidance, which affect the medical device industry and the healthcare industry generally.
- Failures to receive, or delays in receiving, U.S. or foreign regulatory approvals for products.
- Failure to obtain adequate coverage and reimbursement from third party payors for our products.
- Compliance costs and potential liability in connection with U.S. and foreign healthcare regulations, including product recalls, and potential losses resulting from sales of counterfeit and other infringing products.
- Legal costs, insurance expenses, settlement costs and the risk of an adverse decision or settlement related to product liability, patent protection or other litigation.

- Changes in tax laws or their interpretation and changes in statutory tax rates.
- The requirement to provide for a significant liability or to write off, or accelerate depreciation on, a significant asset, including goodwill.
- The success of the Company's research and development activities and other start-up projects.
- Dilution to earnings per share from acquisitions or issuing stock.
- Changes in accounting principles or estimates.
- Environmental risks.
- Other events described in our Securities and Exchange Commission filings, including the "Business" and "Risk Factors" sections in this Annual Report on Form 10-K for the fiscal year ended October 31, 2013, as such Risk Factors may be updated in quarterly filings.

We caution investors that forward-looking statements reflect our analysis only on their stated date. We disclaim any intent to update them except as required by law.

Item 1. Business.

The Cooper Companies, Inc. (Cooper, we or the Company), a Delaware corporation organized in 1980, is a global medical device company publicly traded on the NYSE Euronext (NYSE: COO). Cooper is dedicated to being A Quality of Life Company™ with a focus on shareholder value. Cooper operates through two business units, CooperVision, Inc. and CooperSurgical, Inc.

CooperVision is a global manufacturer providing products for contact lens wearers. CooperVision develops, manufactures and markets a broad range of monthly, two-week and single-use contact lenses, featuring advanced materials and optics. CooperVision's products are designed to solve vision challenges such as astigmatism, presbyopia and ocular dryness; with a broad collection of spherical, toric and multifocal contact lenses. CooperVision's products are primarily manufactured at its facilities located in Hampshire, United Kingdom, Juana Diaz, Puerto Rico, and Scottsville, New York. CooperVision distributes products from West Henrietta, New York, Fareham, United Kingdom, Liege, Belgium, and various smaller international distribution facilities.

CooperSurgical focuses on supplying women's health clinicians with products and treatment options to improve the delivery of healthcare to women. CooperSurgical's primary objectives include internal growth and growth through acquisitions to expand its core businesses and the introduction of advanced technology-based products to aid clinicians in the management and treatment of commonly seen conditions. CooperSurgical customers are healthcare professionals and institutions providing care to and for women. CooperSurgical products support the point of healthcare delivery in the hospital, clinicians office and fertility clinics. CooperSurgical's major manufacturing and distribution facilities are located in Trumbull, Connecticut, Malov, Denmark, Pasadena, California, Stafford, Texas, Golden, Colorado, and Berlin, Germany.

CooperVision and CooperSurgical each operate in highly competitive environments. Competition in the medical device industry involves the search for technological and therapeutic innovations. Both of Cooper's businesses compete primarily on the basis of product quality and differentiation, technological benefit, service and reliability.

COOPERVISION

CooperVision competes in the worldwide soft contact lens market and services three primary regions: the Americas, EMEA (Europe, Middle East and Africa) and Asia Pacific. The contact lens market has two major product categories:

- Spherical lenses including lenses that correct near- and farsightedness uncomplicated by more complex visual defects.
- Toric and multifocal lenses including lenses that, in addition to correcting near- and farsightedness, address more complex visual defects such as astigmatism and presbyopia by adding optical properties of cylinder and axis, which correct for irregularities in the shape of the cornea.

In order to achieve comfortable and healthy contact lens wear, products are sold with recommended replacement schedules, often defined as modalities, with the primary modalities being single-use, two-week and monthly.

CooperVision offers spherical, aspherical, toric, multifocal and toric multifocal lens products in most modalities. We believe that in order to compete successfully in the numerous niches of the contact lens market, companies must offer differentiated products that are priced competitively and manufactured efficiently. CooperVision believes that it is the only contact lens manufacturer to use three different manufacturing processes to produce its lenses: lathing, cast molding and FIPS™, a cost-effective combination of lathing and molding. This manufacturing flexibility allows CooperVision to compete in its markets by:

- Producing high, medium and low volumes of lenses made with a variety of materials for a broader range of market niches: single-use, two-week, monthly and quarterly disposable sphere and toric lenses and custom toric lenses for patients with a high degree of astigmatism.

- Offering a wide range of lens parameters, leading to a higher rate of successful fitting for practitioners and better visual acuity for patients.

Sales of contact lenses utilizing silicone hydrogel materials, a major product material in the industry, have grown significantly. Silicone hydrogel materials supply a higher level of oxygen to the cornea, as measured by the transmissibility of oxygen through a given thickness of material, or “dk/t,” than traditional hydrogel lenses. Silicone hydrogel lenses now represent a significant portion of CooperVision's contact lens sales and our Biofinity® brand is CooperVision's leading product line. Under the Biofinity brand, CooperVision has launched monthly silicone hydrogel spherical, toric and multifocal lens products over the past five years. CooperVision has also launched two-week silicone hydrogel spherical and toric lens products under our Avaira® brand. In fiscal 2013, we launched MyDay™, our single-use spherical silicone hydrogel lens, in Europe.

In addition, CooperVision lenses compete based on providing superior comfort through the use of lens edge technology. CooperVision lenses have a round to partial round edge which we believe increases comfort. CooperVision's Proclear® line of spherical, toric and multifocal lenses are manufactured with omafilcon, a material that incorporates Phosphorylcholine (PC) Technology™ that helps enhance tissue-device compatibility. Proclear lenses are the only lenses with FDA clearance for the claim "… may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms relating to dryness during lens wear." Mild discomfort relating to dryness during lens wear is a condition that often causes patients to discontinue contact lens wear.

In addition to its PC Technology™ and silicone hydrogel product offerings, CooperVision competes in the contact lens market with its traditional hydrogel products.

Contact Lens Product Sales

Spheres: Net sales of CooperVision's spherical lenses, representing 56 percent of CooperVision's net sales, grew 4 percent in fiscal 2013, as compared to fiscal 2012. Single-use spherical lens net sales, representing 21 percent of net sales, grew 1 percent.

Toric and Multifocal: Net sales of CooperVision's toric lenses, representing 31 percent of CooperVision's net sales, grew 9 percent in fiscal 2013, as compared to fiscal 2012. Multifocal lens net sales, representing 10 percent of net sales, grew 29 percent in fiscal 2013.

Proclear: Net sales of CooperVision's PC Technology products - which consist of spherical, toric and multifocal products, including Biomedics® XC and Proclear® 1 Day - grew 6 percent in fiscal 2013 as compared to fiscal 2012 and represented 25 percent of CooperVision's net sales.

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Silicone Hydrogel: CooperVision's silicone hydrogel spherical, toric and multifocal lens products grew 26 percent in fiscal 2013 as compared to fiscal 2012 and represented 43 percent of CooperVision's net sales as compared to 36 percent in fiscal 2012.

CooperVision Competition

The contact lens market is highly competitive. CooperVision's three largest competitors in the worldwide market and its primary competitors in the spherical, toric and multifocal lens categories of that market are Johnson & Johnson Vision Care, Inc., CIBA Vision (owned by Novartis AG) and Bausch & Lomb Incorporated (owned by Valeant Pharmaceuticals International, Inc.).

Over the past decade, the contact lens industry has experienced a global shift toward silicone hydrogel lenses and toward single-use lenses. CooperVision's primary competitors control the majority of the silicone hydrogel segment of the market. CooperVision was late in entering the silicone hydrogel segment of the market but now has significant sales of monthly and two-week spherical, toric and multifocal silicone hydrogel offerings, and it has recently introduced a silicone hydrogel single-use spherical lens.

In the toric lens market, a similar shift toward silicone hydrogel lenses has occurred but we believe that lens manufacturers also continue to compete to provide the highest possible level of visual acuity and patient satisfaction by offering a wide range of lens parameters, superior wearing comfort and a high level of customer service, both for patients and contact lens practitioners. CooperVision competes based on its three manufacturing processes yielding wider ranges of toric lens parameters, providing wide choices for patient and practitioner and superior visual acuity, as well as by offering excellent customer service, including high standards of on-time product delivery.

CooperVision's primary competitors have greater financial resources and larger research and development budgets and sales forces. CooperVision seeks to offer a high level of customer service through its direct sales organizations around the world and through telephone sales and technical service representatives who consult with eye care professionals about the use of the Company's lens products.

CooperVision also competes with manufacturers of eyeglasses and with refractive surgical procedures that correct visual defects. CooperVision believes that its contact lenses will continue to compete favorably against eyeglasses and there are opportunities for contact lenses to gain market share, particularly in markets where the penetration of contact lenses in the vision correction market is low. CooperVision also believes that laser vision correction is not a significant threat to its sales of contact lenses.

COOPERSURGICAL

CooperSurgical offers a broad array of products used in the care and treatment of women's health. The Company participates in the women's healthcare market through offering quality products, innovative technologies and superior service to clinicians worldwide. CooperSurgical collaborates with clinicians to identify products and new technologies from disposable products to sophisticated instruments and equipment. The result is a broad portfolio of products that aid in the delivery of improved clinical outcomes that healthcare professionals use routinely in the diagnosis and treatment of a wide spectrum of women's health issues.

Since its inception in 1990, CooperSurgical has steadily grown its market presence and distribution system by developing products and acquiring products and companies that complement its business model.

Acquisition of Origio
In July 2012, CooperSurgical completed a voluntary tender offer for the outstanding shares of Origio a/s. Origio is a global in-vitro fertilization (IVF) medical device company that develops, manufactures and distributes highly specialized products that target IVF treatment with a goal to make fertility treatment safer, more efficient and convenient. Based in Malov, Denmark, Origio, with approximately 320 employees, is a leader in delivering innovative Assisted Reproductive Technology (ART) solutions that enhance the work of ART professionals to the benefit of families. With 13 subsidiaries and several distributors, Origio has a worldwide presence with a broad product portfolio for the ART market along with professional training programs.

Market for Women's Healthcare

CooperSurgical participates in the market for women's healthcare with its diversified product lines of over 600 products. CooperSurgical products are in three major categories based on the point of healthcare delivery: hospitals, obstetricians and gynecologists (ob/gyns) medical offices and fertility clinics.

Based on United States Census estimates, CooperSurgical expects patient visits to United States ob/gyns to increase over the next decade. Driving this growth is an increasing base of reproductive age women, a large and stable middle-aged population and a rapidly growing population of women over the age of 65. CooperSurgical believes that the resurgence of population growth in the reproductive age group will result in increased office visits related to birth control and childbearing. CooperSurgical expects growth in fertility treatments as more women choose to delay childbearing to the mid-thirties and beyond. Office visit activity related to menopausal problems, including abnormal bleeding, incontinence and osteoporosis, are also expected to increase slightly over the next decade. CooperSurgical believes that in the past clinicians primarily saw women only during their reproductive years. Now, with new treatment options available and a more educated population, CooperSurgical expects the relationship between the patient and clinician will continue into the middle years and later.

Another trend in the market for women's healthcare includes the migration of ob/gyn clinicians away from private practice ownership and toward aligning with group practices or employment with hospitals and health systems. CooperSurgical believes that the market factors that are driving this trend will continue in the near term.

While general medical practitioners play an important role in women's primary care, the ob/gyn specialist is the primary market for associated medical devices.

Some significant features of this market are:

- Patient visits are for annual checkups, cancer screening, menstrual disorders, vaginitis (inflammation of vaginal tissue), treatment of abnormal Pap smears, osteoporosis (reduction in bone mass) and the management of menopause, pregnancy and reproductive management.

- Ob/gyns traditionally provide the initial evaluation for women and their partners who seek infertility assistance. Ovulatory drugs and intrauterine insemination (IUI) are common treatments of these cases along with embryo transfer procedures.

- Osteoporosis and incontinence have become frequent diagnoses as the female population ages. Early identification and treatment of these conditions will both improve women's health and help reduce overall costs of treatment.

- Sterilization is a frequently performed surgical procedure.

- Hysterectomy, one of the most commonly performed surgical procedures, is increasingly performed using a laparoscopic approach.

- The trend to move hospital-based procedures to an office or clinical setting is continuing as seen with the endometrial ablation procedure.

CooperSurgical's Fiscal 2013 Net Sales Growth

During fiscal 2013, CooperSurgical's net sales grew 25 percent, or 3 percent excluding acquisitions, to $319.4 million from $255.9 million in fiscal 2012, representing 20 percent of Cooper's net sales in fiscal 2013 compared to 18 percent in fiscal 2012. With the acquisition of Origio in July 2012, sales of fertility products now represent 33 percent of CooperSurgical's net sales as compared to 16 percent in fiscal 2012.

CooperSurgical Competition

CooperSurgical focuses on selected segments of the women's healthcare market, supplying diagnostic products and surgical instruments and accessories. In some instances, CooperSurgical offers all of the items needed for a complete procedure. CooperSurgical believes that opportunities exist for continued market consolidation of smaller technology-driven firms that generally offer only one or two product lines. Most are privately owned or divisions of public companies including some owned by companies with greater financial resources than Cooper.

Competitive factors in these segments include technological and scientific advances, product quality, price, customer service and effective communication of product information to physicians and hospitals. CooperSurgical competes based on its sales and marketing expertise and the technological advantages of its products. CooperSurgical's strategy includes developing and acquiring new products, including those used in new medical procedures. As CooperSurgical expands its product line, it also offers training for medical professionals in the appropriate use of its products.

CooperSurgical is seeking to expand its presence in the significantly larger hospital and outpatient surgical procedure segment of the market that is at present dominated by bigger competitors such as Johnson & Johnson's Ethicon Endo-Surgery and Ethicon Women's Health and Urology companies, Boston Scientific, Gyrus ACMI and Covidien. These competitors have well established positions within the operating room

environment. CooperSurgical intends to leverage its relationship with gynecologic surgeons and focus on devices specific to gynecologic surgery to facilitate its expansion within the surgical segment of the market.

RESEARCH AND DEVELOPMENT

Cooper employs about 245 people in its research and development and manufacturing engineering departments. Most of these employees are in CooperVision. CooperVision product development and clinical research is supported by internal and external specialists in lens design, formulation science, polymer chemistry, clinical trials, microbiology and biochemistry. CooperVision's research and development activities primarily include programs to develop new contact lens designs.

CooperSurgical conducts research and development in-house and also has consulting agreements with external surgical specialists. CooperSurgical's research and development activities include the design and upgrading of surgical procedure devices, the upgrade and expansion of CooperSurgical's portfolio of assisted reproductive technology products, including Origio products, as well as products within the general obstetrics and gynecology offerings.

Cooper-sponsored research and development expenditures during fiscal 2013, 2012 and 2011 were $58.8 million, $51.7 million and $43.6 million, respectively. Research and development expenditures represented 4 percent of net sales in fiscal 2013 and 2012, and 3 percent in 2011. During fiscal 2013, CooperVision represented 79 percent and CooperSurgical represented 21 percent of the total research and development expenses. We did not participate in any customer-sponsored research and development programs during fiscal 2011 - 2013.

GOVERNMENT REGULATION

Medical Device Regulation

Our products are medical devices subject to extensive regulation by the United States Food and Drug Administration (FDA) in the United States and other regulatory bodies abroad. FDA regulations govern, among other things, medical device design and development, testing, manufacturing, labeling, storage, recordkeeping, premarket clearance or approval, advertising and promotion, and sales and distribution. Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior 510(k) clearance or prior premarket approval (PMA) from the FDA. A majority of the medical devices we currently market have received FDA clearance through the 510(k) process or approval through the PMA process. Because we cannot be assured that any new products we develop, or any product enhancements, will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancements may occur.

Device Classification

The FDA classifies medical devices into one of three classes - Class I, II or III - depending on the degree of risk associated with each medical device and the extent of control needed to ensure its safety and effectiveness. Both CooperVision and CooperSurgical develop and market medical devices under different levels of FDA regulation depending on the classification of the device. Class III devices, such as flexible and extended wear contact lenses, require extensive premarket testing and approval, while Class I and II devices require lower levels of regulation. The majority of CooperSurgical's products are Class II devices.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's

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Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (General Controls). Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. Pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process.

Class III devices are those devices which have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the premarket approval process described below. Premarket approval applications (and supplemental premarket approval applications) are subject to significantly higher user fees under MDUFMA than are 510(k) premarket notifications.

510(k) Clearance Pathway

When we are required to obtain a 510(k) clearance for a device that we wish to market, we must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of premarket approval applications. By regulation, the FDA is required to respond to a 510(k) premarket notification within 90 days of submission of the notification. As a practical matter, clearance can take significantly longer. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use of the device, into Class III.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that changes its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. In these circumstances, a manufacturer also may be subject to significant regulatory fines or penalties. We have made and plan to continue to make additional product enhancements and modifications to our devices that we believe do not require new 510(k) clearances.

Premarket Approval Pathway

A PMA application must be submitted if the device cannot be cleared through the 510(k) premarket notification procedures. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

After a PMA application is complete, the FDA begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted PMA application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information, including clinical data, or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation (QSR). New PMA applications or PMA application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for an investigational device exemption (IDE) to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that the potential benefits of testing the device in humans outweighs the risks and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by both the FDA and the appropriate institutional review boards at the clinical trial sites. All of Cooper's currently marketed products have been cleared by all appropriate regulatory agencies, and Cooper has no product currently being marketed under an IDE.

Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; new FDA unique device identifier legislation which requires changes to labeling and packaging; the recently enacted Physician Payments Sunshine Act requiring the reporting of certain payments to health care practitioners made after August 1, 2013; and medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: fines, injunctions and civil penalties; recall, seizure or import holds of our products; operating restrictions, suspension of production; refusing our request for 510(k) clearance or premarket approval of new products; withdrawing 510(k) clearance or premarket approvals that are already granted and criminal prosecution.

Even if regulatory approval or clearance of a medical device is granted, the FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. FDA regulations prohibit a manufacturer from promoting a device for an unapproved or "off-label" use. Failure to comply with this prohibition on "off-label" promotion can result in enforcement action by the FDA, including, among other things, warning letters, fines, injunctions, consent decrees and civil or criminal penalties.

Foreign Regulation

Health authorities in foreign countries regulate Cooper's clinical trials and medical device sales. The regulations vary widely from country to country. Even if the FDA has approved a product, the regulatory agencies in each country must approve new products before they may be marketed there. The worldwide Medical Device regulations are increasing, with many countries becoming regulated for the first time. For example, Hong Kong and Singapore are now regulated and following the Global Harmonization Task Force model for regulating medical devices. These emerging regulated countries require the same rigorous safety data compiled in pre-clinical and clinical studies for the rest of the world. Japan has one of the most rigorous regulatory systems in the world and requires in-country clinical trials. The Japanese quality and regulatory standards remain stringent even with the more recent harmonization efforts and updated Japanese regulations. China is also updating its regulations and is requiring rigorous in-country product testing.

These regulatory procedures require a considerable investment in time and resources and usually result in a substantial delay between new product development and marketing. If the Company does not maintain compliance with regulatory standards or if problems occur after marketing, product approval may be withdrawn.

In addition to FDA regulatory requirements, the Company also maintains ISO 13485 certification and CE mark approvals for its products. A CE mark is an international symbol of adherence to certain standards and compliance with applicable European medical device requirements. These quality programs and approvals are required by the European Medical Device Directive and must be maintained for all products intended to be sold in the European market. The ISO 13485 Quality Measurement System registration is now also required for registration of products in Asia Pacific and Latin American countries. In order to maintain these quality benchmarks, the Company is subjected to rigorous biannual reassessment audits of its quality systems and procedures.

Other Health Care Regulation

We may be subject to various federal, state and foreign laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, and laws pertaining to healthcare privacy and security. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs and TRICARE. Similarly if the physicians or other providers or entities with whom we do business are found to be noncompliant with applicable laws, they may be subject to sanctions, which could indirectly have a negative impact on our business, financial conditions and results of operations. While we believe that our operations are in material compliance with such laws, as applicable to us, because of the complex and far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws.