COOPER COMPANIES INC
Form 10-K
December 21, 2018

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, 2018
COMMISSION FILE NO. 001-08597

_____

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 o
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 o 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 o
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).
Yes x No o
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.

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o
Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

On November 30, 2018, there were 48,938,208 shares of the registrant's common stock held by non-affiliates with aggregate market value of $11.3 billion on April 30, 2018, 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, 2018: 49,232,061
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 2019	Part III

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

Annual Report on Form 10-K
for the Fiscal Year Ended October 31, 2018

Table of Contents

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

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 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. 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, including all statements regarding acquisitions including the acquired companies' financial position, market position, product development and business strategy, expected cost synergies, expected timing and benefits of the transaction, difficulties in integrating entities or operations, as well as estimates of our and the acquired entities' future expenses, sales and earnings per share are forward-looking. 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 the global or regional general business, political and economic conditions, including the impact of continuing uncertainty and instability of certain countries that could adversely affect our global markets, and the potential adverse economic impact and related uncertainty caused by these items, including but not limited to, the United Kingdom’s election to withdraw from the European Union and escalating global trade barriers including additional tariffs.

- Foreign currency exchange rate and interest rate fluctuations including the risk of fluctuations in the value of foreign currencies or interest rates that would decrease our revenues and earnings.

- Changes in tax laws or their interpretation and changes in statutory tax rates, including but not limited to, the U.S., the United Kingdom and other countries with proposed changes to tax laws, some of which may affect our taxation of earnings recognized in foreign jurisdictions and/or negatively impact our effective tax rate.

- Our existing indebtedness and associated interest expense, most of which is variable and impacted by rate increases, which could adversely affect our financial health or limit our ability to borrow additional funds.

- Acquisition-related adverse effects including the failure to successfully obtain the anticipated revenues, margins and earnings benefits of acquisitions, integration delays or costs and the requirement to record significant adjustments to the preliminary fair value of assets acquired and liabilities assumed within the measurement period, required regulatory approvals for an acquisition not being obtained or being delayed or subject to conditions that are not anticipated, adverse impacts of changes to accounting controls and reporting procedures, contingent liabilities or indemnification obligations, increased leverage and lack of access to available financing (including financing for the acquisition or refinancing of debt owed by us on a timely basis and on reasonable terms).

- Compliance costs and potential liability in connection with U.S. and foreign laws and health care regulations pertaining to privacy and security of third- party information, such as HIPAA in the U.S. and the General Data Protection Regulation requirements which took effect in Europe on May 25, 2018, including but not limited to those resulting from data security breaches.

- A major disruption in the operations of our manufacturing, accounting and financial reporting, research and development, distribution facilities or raw material supply chain due to integration of acquisitions, natural disasters or other causes.

- A major disruption in the operations of our manufacturing, accounting and financial reporting, research and development or distribution facilities due to technological problems, including any related to our information systems maintenance, enhancements or new system deployments, integrations or upgrades.

- Disruptions in supplies of raw materials, particularly components used to manufacture our silicone hydrogel lenses.

- New U.S. and foreign government laws and regulations, and changes in existing laws, regulations and enforcement guidance, which affect areas of our operations including, but not limited to, those affecting the health care industry, including the contact lens industry specifically and the medical device or pharmaceutical industries generally.

- Legal costs, insurance expenses, settlement costs and the risk of an adverse decision, prohibitive injunction or settlement related to product liability, patent infringement or other litigation.

- Limitations on sales following product introductions due to poor market acceptance.

- New competitors, product innovations or technologies, including but not limited to, technological advances by competitors, new products and patents attained by competitors, and competitors' expansion through acquisitions.

- Reduced sales, loss of customers and costs and expenses related to product recalls and warning letters.

- Failure to receive, or delays in receiving, U.S. or foreign regulatory approvals for products.

- Failure of our customers and end users to obtain adequate coverage and reimbursement from third-party payors for our products and services.

- The requirement to provide for a significant liability or to write off, or accelerate depreciation on, a significant asset, including goodwill and idle manufacturing facilities and equipment.

- The success of our research and development activities and other start-up projects.

- Dilution to earnings per share from acquisitions or issuing stock.

- Impact and costs incurred from changes in accounting standards and policies.

- Environmental risks, including increasing environmental legislation and the broader impacts of climate change.

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

- 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, 2018, 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.

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

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™. Cooper operates through two business units, CooperVision and CooperSurgical.

CooperVision is a global manufacturer providing products for contact lens wearers. CooperVision develops, manufactures and markets a broad range of single-use, two-week and monthly contact lenses, featuring advanced materials and optics. CooperVision designs its products to solve vision challenges such as astigmatism, presbyopia, myopia, ocular dryness and eye fatigues; with a broad collection of spherical, toric and multifocal contact lenses. Recent acquisitions also expanded CooperVision's access to myopia management markets with new products, such as orthokeratology (ortho-k) specialty lenses. CooperVision's contact lenses are offered in a variety of materials including silicone hydrogel Aquaform® technology and phosphorylcholine technology (PC) Technology™. CooperVision primarily manufactures its products at its facilities located in the United Kingdom, Puerto Rico, Hungary, Costa Rica and the United States. CooperVision distributes products out of its facilities in the United States, the United Kingdom, Belgium and various smaller international distribution facilities.

CooperSurgical's business competes in the general health care market with a focus on advancing the health of women, babies and families through a diversified portfolio of products and services including medical devices, fertility, genomics, diagnostics, and contraception. CooperSurgical has established its market presence and distribution system by developing products and acquiring companies, products and services that complement its business model. We categorize CooperSurgical product sales based on the point of health care delivery, which includes products used in medical office and surgical procedures, primarily by obstetricians and gynecologists (ob/gyns); and fertility products/equipment and genetic testing services used primarily in fertility clinics and laboratories. CooperSurgical's major manufacturing and distribution facilities are located in Connecticut, Texas, New York, Denmark, Costa Rica, the Netherlands, the United Kingdom and various smaller international locations, with diagnostic facilities located in multiple locations in the United States and internationally in Canada and the United Kingdom. CooperSurgical purchased a manufacturing facility in Costa Rica in November 2017 to consolidate a portion of global manufacturing and is also currently shifting its primary distribution facility from Denmark to Venlo, Netherlands.

CooperVision and CooperSurgical each operate in highly competitive environments. Competition in the medical device industry is dynamic and involves the search for technological and therapeutic innovations. Both of Cooper's businesses compete predominantly 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.

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

- 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 lenses and frequently replaced lenses, which are designed for two-week and monthly replacement.

CooperVision offers spherical, toric, multifocal and toric multifocal lens products in most modalities. We believe that in order to compete successfully in the numerous categories 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. We believe 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, toric and multifocal 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.

Significantly, the market for spherical lenses is growing with the addition of new value-added products, such as spherical lenses to alleviate dry eye symptoms, reduce eye fatigue from use of digital devices and add aspherical optical properties and/or higher oxygen permeable lenses such as silicone hydrogels.

Sales of contact lenses utilizing silicone hydrogel materials continue to grow. 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. We believe our ability to compete successfully with a full range of silicone hydrogel products is an important factor to achieving success in our business. Silicone hydrogel lenses 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 markets monthly silicone hydrogel spherical, toric and multifocal lens products.

CooperVision markets single-use silicone hydrogel with a complete line of spherical, toric and multifocal lenses under our clariti® 1day brand and single-use silicone hydrogel spherical and toric lenses under our MyDay® brand. We also compete in the traditional hydrogel single-use product segment with several lenses including our Proclear® 1 Day lenses. We believe the global market for single-use contact lenses will continue to grow and that our competitive silicone hydrogel and traditional hydrogel product offerings represent an opportunity for our business.

We manufacture silicone hydrogel Biofinity brand spherical, toric and multifocal contact lenses, Avaira Vitality brand spherical and toric lenses and MyDay brand spherical and toric lenses using proprietary Aquaform technology to increase oxygen transmissibility for longer wear.

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

CooperVision believes that our key accounts which include optical chains, global retailers, certain buying groups and mass merchandisers are growing faster than the overall market and are expected to have a sustainable long-term

growth trend. We are focused on supporting the growth of all our customers by

investing in selling, promotional and advertising activities. Further, we are increasing investment in our distribution and packaging capabilities to support the growth of our business and to continue to provide quality service with our industry leading SKU range and customized offerings.

CooperVision is focused on greater worldwide market penetration of recently introduced products, and we continue to expand our presence in existing and emerging markets, including through acquisitions. In fiscal 2018, CooperVision acquired Paragon Vision services, a leading provider of ortho-k, specialty contact lenses and oxygen permeable rigid contact lens material, and Blueyes Ltd. (Blueyes), a long-standing distribution partner, with a leading position in the distribution of contact lenses to the Optical and Pharmacy sector in Israel. In fiscal 2017, we acquired Procornea Holding B.V. (Procornea), a Netherlands based manufacturer of specialty contact lenses, which expands CooperVision’s access to myopia (nearsightedness) management markets with new products, and Grand Vista LLC, a distributor in Russia of soft contact lenses.

Contact Lens Product Sales
CooperVision Competition

The contact lens market is highly competitive. CooperVision's 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., Bausch Health Companies Inc. and Alcon (formerly CIBA Vision Corporation) owned by Novartis AG.

CooperVision's competitors may have greater financial resources, larger research and development budgets, larger sales forces, greater market penetration and/or larger manufacturing volumes. 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 our lens products.

CooperVision also competes with manufacturers of eyeglasses and with refractive surgical procedures that correct visual defects including laser vision correction. CooperVision believes that laser vision correction is not a significant threat to its sales of contact lenses based on the growth of the contact lens market over the past decade.

CooperVision competes in the silicone hydrogel segment of the market with its following products: Biofinity monthly spherical, toric and multifocal lenses; Avaira Vitality™ two-week spherical and toric

lenses; clariti 1day brand of single-use sphere, toric and multifocal lenses; and MyDay single-use spherical and toric lenses. The clariti 1day and MyDay brands of single-use contact lenses provide CooperVision with the broadest product portfolio in the single-use silicone hydrogel market.

In addition to a broad offering of silicone hydrogel lenses, CooperVision competes based on the fact that its three manufacturing processes allow CooperVision to produce a broad range of spheres, toric and multifocal lens parameters, which we believe provides wide choices for patient and practitioner and a high level of visual acuity. We also compete based on our customer and professional services. CooperVision believes that 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.

COOPERSURGICAL

CooperSurgical offers a broad array of products and services focused on advancing the health of women, babies and families through a diversified portfolio of products and services including medical devices, fertility, genomics, diagnostics and contraception. The Company offers quality products, innovative technologies and superior services to clinicians and patients worldwide. CooperSurgical collaborates with clinicians to identify products and new technologies from disposable products to diagnostic tests to sophisticated instruments and equipment, to bring new products to market. The result is a broad portfolio of products and services that are intended to aid in the delivery of improved clinical outcomes that health care professionals use routinely in the diagnosis and treatment of a wide spectrum of family and women's health and reproductive issues.

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

CooperSurgical competes in the global in-vitro fertilization (IVF) market with a product portfolio of IVF media and assisted reproductive technology solutions including genetic testing designed to enhance the work of fertility professionals to the benefit of women, babies and families.

We have continued to invest in CooperSurgical's business through the acquisition of companies and product lines for new or complementary products and services for the IVF process and within the ob/gyn space.

In fiscal 2018, we acquired the assets of the PARAGARD Intrauterine Device (IUD) business (PARAGARD) from Teva Pharmaceuticals Industries Limited (Teva). This acquisition broadens and strengthens CooperSurgical's current women's health product portfolio in office and surgical procedures. PARAGARD® is the only hormone-free, long lasting, reversible contraceptive option approved by FDA available in the United States, and IUDs represent a large and growing segment of the contraceptive market. We also acquired in fiscal 2018, The LifeGlobal Group (LifeGlobal) which was a privately held company that specializes primarily in the IVF media marketplace. In fiscal 2017, we acquired Wallace, the IVF segment of Smiths Medical International Ltd. We intend to continue investing in CooperSurgical's business with the goal of expanding our integrated solutions model within the areas of family health, fertility and diagnostics.

Market for Women's and Family Reproductive Health Care

CooperSurgical participates in the market for family health care with its diversified product lines in three major categories based on the point of health care delivery: hospitals and surgical centers, obstetricians' and gynecologists' (ob/gyns) medical offices and fertility clinics.

9

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

CooperSurgical expects patient visits to ob/gyns in the United States to increase over the next decade. Office visit activity related to menopause, abnormal bleeding, incontinence and osteoporosis, are expected to increase slightly over the next decade. Driving the growth is a growing population of women over the age of 65 (according to the United States Census estimates), a large and stable middle-aged population, and a steady number of reproductive age women with increasing fertility issues as well as women interested in contraception that is reversible such as with the PARAGARD® IUD. CooperSurgical expects growth in fertility treatments as more women choose to delay childbearing to the mid-thirties and beyond.

Another trend in the market for women's health care includes the migration of ob/gyn clinicians away from private practice ownership and toward aligning with group practices or employment with hospitals and health care systems. This trend includes the increasing influence of supply chain controls, such as value analysis committees, on product evaluation and procurement. CooperSurgical believes that the market factors that are driving this trend will continue in the near term. We believe our broad product portfolio can be a benefit in this changing environment as health systems look to standardize and consolidate vendors.

Recent trends in the United States market include the development of more cost-effective health care delivery models, including moving treatment out of hospitals and surgery centers and into the office setting without compromising care. We expect this trend to continue.

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

- We believe that approximately one-third of the office visits to ob/gyns are patients seeking diagnosis and treatment for the symptoms of abnormal uterine bleeding.

- A high proportion of office visits are for contraceptive 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 in these cases.

- IVF is performed by reproductive endocrinologists, a subgroup of ob/gyns, along with partner embryologists.

- 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 procedure.

- Hysterectomy is one of the most commonly performed surgical procedures.

10

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

- Hysteroscopy is commonly used in the evaluation of abnormal uterine bleeding.

- The trend to move hospital-based procedures to an office or clinical setting is continuing as a method to reduce cost to the health care system without compromising clinical outcomes.

- Increased awareness of improved IVF outcomes with preimplantation genetic screening will continue.

Women's and Family Reproductive Health Care Product Sales
CooperSurgical Competition

CooperSurgical focuses on selected segments of the family and women's health care market, supplying diagnostic products, services, 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, fertility clinics and hospitals. CooperSurgical competes based on our sales and marketing expertise and the technological advantages of our products. CooperSurgical's strategy includes developing and acquiring new products, including those used in new medical procedures. As CooperSurgical expands its product line, we also offer educational programs for medical professionals in the appropriate use of our products.

CooperSurgical is seeking to expand our 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, Boston Scientific, Hologic, Olympus and Medtronic. These competitors have well-established positions within the operating room environment. CooperSurgical intends to leverage our relationship with gynecologic surgeons and focus on devices specific to gynecologic surgery to facilitate our expansion within the surgical segment of the market.

CooperSurgical also competes in the fertility category of the women's health care market. We have broad product offerings for fertility evaluations and IVF procedures by ob/gyns, reproductive endocrinologists and embryologists. These include products for use by the ob/gyns in their offices for initial evaluations with office-based hysteroscopy and first line treatments such as intrauterine insemination. In fertility

clinics, our products include media, micro tools and lab equipment; and to improve IVF outcomes we offer screening testing services intended to increase implantation rates and decrease miscarriages.

CooperSurgical intends to leverage our relationship with fertility clinics to expand our presence in the fertility market against competitors in the media and microtools categories that include Vitrolife, Cook and Irvine Scientific and competitors in fertility and familial reproductive genetic testing that include Natera, Invitae and Igenomix.

With the acquisition of PARAGARD in fiscal 2018, CooperSurgical now competes in the IUD market. PARAGARD is the only non-hormonal IUD option in the United States and has a 10-year use indication. In the United States, where all IUDs are regulated as pharmaceuticals, we compete with manufacturers of hormonal IUDs including Bayer and Allergan. Outside of the United States, non-hormonal IUDs are more typically regulated as devices and are sold by a number of manufacturers. Currently, PARAGARD is not sold outside of the United States.

RESEARCH AND DEVELOPMENT

The Company employs approximately 258 people in research and development. 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 and manufacturing technology, along with improving formulations and existing products.

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

Cooper-sponsored research and development expenditures during fiscal 2018, 2017 and 2016, were $84.8 million, $69.2 million and $65.4 million, respectively. As a percentage of sales, research and development expenditures were 3% in fiscal 2018, 2017 and 2016. During fiscal 2018, CooperVision represented 64% and CooperSurgical represented 36% of the total research and development expenses, compared to 69% and 31% in fiscal 2017 for CooperVision and CooperSurgical respectively.

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

GOVERNMENT REGULATION

Medical Device and Pharmaceutical Regulation

Most of our products are medical devices subject to extensive regulation by the FDA in the United States and other regulatory bodies abroad. The Federal Food, Drug, and Cosmetic Act (FDCA) and FDA regulations govern, among other things, medical device design and development, testing, manufacturing, labeling, storage, record keeping, 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 notice to the FDA requesting clearance for commercial distribution under Section 510(k) of the FDCA, or 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 exempt from the premarket clearance or approval requirements or will be subject to the shorter 510(k) clearance process rather than the PMA 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 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, such as performance standards, post-market surveillance, FDA guidelines or particularized labeling requirements. 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 deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or 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 other special controls such as those listed above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the PMA process described below. PMA applications (and supplemental PMA 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 Class I or Class II 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 in the United States before May 28, 1976, for which the FDA has not yet called for the submission of PMA applications. The FDA aims to respond to a 510(k) premarket notification within 90 days of submission of the notification, but as a practical matter, clearance can take significantly longer. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is not substantially equivalent to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the de novo process.

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 or if the device has been previously classified as Class III. 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.

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. 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, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within 180 days after the FDA issues such request. 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), which requires manufacturers to implement and follow elaborate design, testing, control, documentation and other quality assurance procedures in the device design and manufacturing process.

The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. 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 PMA process. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials for Medical Devices

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