GREATBATCH, INC. Form 10-K March 02, 2010

UNITED STATES 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 January 1, 2010 Commission File Number 1-16137 GREATBATCH, INC.

(Exact name of Registrant as specified in its charter)

Delaware

16-1531026

(State of Incorporation)

(I.R.S. Employer Identification No.)

10000 Wehrle Drive Clarence, New York 14031 (Address of principal executive offices) (716) 759-5600

(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 Preferred Stock Purchase Rights New York Stock Exchange

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 o No b

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 \flat

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 \flat No o Indicate by checkmark 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 o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. o 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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o

Accelerated filer b

Non- accelerated filer o

Smaller reporting company o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No by The aggregate market value of common stock of Greatbatch, Inc. held by non-affiliates as of July 2, 2009 (last business day of most recently completed second fiscal quarter), based on the last sale price of \$22.00, as reported on

the New York Stock Exchange: \$501.2 million. Solely for the purpose of this calculation, shares held by directors and officers and 10 percent shareholders of the Registrant have been excluded. Such exclusion should not be deemed a determination by or an admission by the Registrant that these individuals are, in fact, affiliates of the Registrant. Shares of common stock outstanding on March 2, 2010: 23,216,407

DOCUMENTS INCORPORATED BY REFERENCE

The following documents, in whole or in part, are specifically incorporated by reference in the indicated part of the Company s Proxy Statement:

Document

Proxy Statement for the 2010 Annual Meeting of Stockholders

Part

Part III, Item 10

Directors, Executive Officers and Corporate Governance

Part III, Item 11

Executive Compensation

Part III, Item 12

Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Part III, Item 13

Certain Relationships and Related Transactions, and

Director Independence

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Principal Accounting Fees and Services

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PART I

ITEM 1. BUSINESS OVERVIEW

Wilson Greatbatch, co-inventor of the first successful implanted pacemaker, founded the predecessor to Greatbatch, Inc. in 1970 to develop long-lived primary batteries to fuel pacemakers. His passion for reliability and innovation is the foundation for Greatbatch s full portfolio of capabilities and offerings. Every day, Greatbatch supports and empowers its customers in their pursuit of revolutionary technology solutions. Greatbatch, Inc. provides these innovative technologies to industries that depend on reliable, long-lasting performance. When used in this report, the terms we, us, our and the Company mean Greatbatch, Inc. and its subsidiaries. We believe that our proprietary technology, close customer relationships, multiple product offerings, market leadership and dedication to quality provide us with competitive advantages and create a barrier to entry for potential market entrants.

We operate our business in two reportable segments Greatbatch Medical and Electrochem Solutions (Electrochem). During 2009, we rebranded our Implantable Medical Component (IMC) segment as Greatbatch Medical. The Greatbatch Medical segment designs and manufactures systems, components and devices for the Cardiac Rhythm Management (CRM), Neuromodulation, Vascular Access and Orthopaedic markets. Our Greatbatch Medical customers include large multi-national original equipment manufacturers (OEMs). Greatbatch Medical products include: 1) batteries, capacitors, filtered and unfiltered feedthroughs, engineered components and enclosures used in Implantable Medical Devices (IMDs); 2) instruments and delivery systems used in hip and knee replacement, trauma and spine surgeries as well as hip, knee and shoulder implants; and 3) introducers, catheters, steerable sheaths and implantable stimulation leads. Additionally, Greatbatch Medical offers value-added assembly and design engineering services for medical systems and devices within the markets in which it operates.

Electrochem is a leader in technology solutions for critical industrial applications, including customized battery power and wireless sensing systems. Originating from the lithium cell invented for the implantable pacemaker by our founder, Wilson Greatbatch, our technology and superior quality and reliability is utilized in markets world-wide. The Company is a Delaware corporation that was incorporated in 1997 and since that time has completed the following acquisitions:

Acquisition date	Acquired company	Business at time of acquisition
July 1997	Wilson Greatbatch Ltd.	Founded in 1970, designed and manufactured batteries for IMD s and commercial applications.
August 1998	Hittman Materials and Medical Components, Inc.	Founded in 1962, designed and manufactured ceramic and glass feedthroughs and specialized porous coatings for electrodes used in IMDs.
August 2000	Battery Engineering, Inc.	Founded in 1983, designed and manufactured high-energy density batteries for industrial, commercial, military and medical applications.

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Acquisition date	Acquired company	Business at time of acquisition
June 2001	Sierra-KD Components division of Maxwell Technologies, Inc.	Founded in 1986, designed and manufactured ceramic electromagnetic filtering capacitors and integrated them with wire feedthroughs for use in IMDs as well as military, aerospace and commercial applications.
July 2002	Globe Tool and Manufacturing Company, Inc.	Founded in 1954, designed and manufactured precision enclosures used in IMDs and commercial products used in the aerospace, electronic and automotive sectors.
March 2004	NanoGram Devices Corporation	Founded in 1996, developed nanoscale materials for battery and medical device applications.
April 2007	BIOMEC, Inc.	Established in 1998, provided medical device design and component integration to early-stage and established customers.
June 2007	Enpath Medical, Inc.	Founded in 1981, designed, developed, and manufactured venous introducers and dilators, implantable leadwires, steerable sheaths and steerable catheters.
October 2007	IntelliSensing LLC	Founded in 2005, designed and manufactured battery-powered wireless sensing solutions for commercial applications.
November 2007	Quan Emerteq LLC	Founded in 1998, designed, developed, and manufactured catheters, stimulation leadwires, microcomponents and assemblies.
November 2007	Engineered Assemblies Corporation	Founded in 1984, designed and integrated custom battery solutions and electronics focused on rechargeable systems.
January 2008	P Medical Holding SA	Founded in 1994, designed, manufactured and supplied delivery systems, instruments and implants for the orthopaedic industry.
February 2008	DePuy Orthopaedics Chaumont, France manufacturing facility	Manufactured hip and shoulder implants for DePuy.
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FINANCIAL STATEMENT YEAR END

We utilize a fifty-two, fifty-three week fiscal year ending on the Friday nearest December 31st. Fiscal years 2009, 2008 and 2007 ended on January 1, 2010, January 2, 2009 and December 28, 2007, respectively. Fiscal year 2008 contained fifty-three weeks while fiscal years 2009 and 2007 contained fifty-two weeks.

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SEGMENT INFORMATION

We operate our business in two reportable segments Greatbatch Medical and Electrochem. Segment information including sales from external customers, profit or loss, and assets by segment as well as sales from external customers and long-lived assets by geographic area are set forth at Note 13 Business Segment Information of the Notes to Consolidated Financial Statements contained at Item 8 of this report.

GREATBATCH MEDICAL

CRM & Neuromodulation An IMD is an instrument that is surgically inserted into the body to provide diagnosis and/or therapy. One sector of the IMD market is CRM, which is comprised of devices such as implantable pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and cardiac resynchronization therapy with backup defibrillation devices (CRT-D). A new emerging sector of the IMD market is neuromodulation, which is comprised of pacemaker-type devices that stimulate nerves for the treatment of various conditions. Beyond approved therapies of pain control, incontinence, Parkinson s disease and epilepsy, nerve stimulation for the treatment of other disabilities such as migraines, obesity and depression has shown promising results.

The following table sets forth the main categories of battery-powered IMDs and the principal illness or symptom treated by each device:

Device Principal Illness or Symptom

Pacemakers Abnormally slow heartbeat (Bradycardia) ICDs Rapid and irregular heartbeat (Tachycardia)

CRT/CRT-Ds Congestive heart failure

Neurostimulators Chronic pain, movement disorders, epilepsy, obesity or depression

Drug pumps Diabetes or chronic pain

We believe that the CRM and Neuromodulation markets continue to exhibit growth fundamentals and that we are well positioned to continue to participate in this market growth. Increased demand is being driven by the following factors:

<u>Advances in medical technology</u> new therapies will allow physicians to use IMDs to treat a wider range of patients with various heart diseases.

New, more sophisticated implantable devices device manufacturers are developing new CRM devices and adding new features to existing products (such as RF telemetry) which require increased energy and power. At the same time, device manufacturers are trying to reduce the size of their devices. We believe that our proprietary batteries and capacitors are well positioned to meet the needs of these more sophisticated, smaller devices.

<u>Expanding patient population</u> the patient groups that are eligible for CRM devices have increased. The number of people in the U.S. that are over age 50 is expected to double in the next 10 years.

<u>Growth within neuromodulation</u> neuromodulation applications are growing at a faster pace than our traditional markets and are expected to expand as new therapeutic applications are identified.

<u>New performance requirements</u> government regulators are increasingly requiring that IMDs be protected from electromagnetic interference (EMI).

Global markets increased market penetration worldwide.

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Vascular Access Includes introducers and catheters that deliver therapies for coronary and neurovascular disease, peripheral vascular disease, neuromodulation, CRM, as well as products for medical imaging and drug and pharmaceutical delivery. Introducers enable physicians to create a conduit through which they can insert infusion catheters, implantable ports, pacemaker leads and other therapeutic devices into a blood vessel. A catheter is a tube that can be inserted into a blood vessel to allow drainage, injection of fluids, or access by surgical instruments. In order to introduce a catheter or pacemaker lead into a vein, a hypodermic needle is first used to access the vein. A guide wire is then inserted through the hypodermic needle and the needle is removed. An introducer consists of a hollow sheath and a dilator which is inserted over the guide wire to expand the opening. The guide wire and dilator are then removed, leaving only the hollow sheath through which the catheter or pacemaker lead is introduced. Once the catheter or pacemaker lead is in place, the vessel introducer sheath is removed. We market these introducer and catheter products in kits that contain the disposable devices necessary to perform procedures and also in bulk for packaging by the customer with its own devices.

These products seek to capitalize on the growth in the Neuromodulation and CRM markets, specifically with new indications for neuromodulation devices and procedures. In addition, we continue to see strong growth in the vascular markets because of stent delivery procedures, peripheral-vascular disease therapies, and new indications for tissue extraction or ablation. In addition to those factors that are driving CRM and Neuromodulation markets, increased demand is also being driven by continued focus on minimally invasive procedures. Patients and health care providers are looking for minimally invasive technologies to treat disease and are expanding their use of both catheter based procedures and associated vascular access therapies.

Orthopaedic Orthopaedic implants are used in reconstructive surgeries to replace or repair hips, knees and other joints, such as shoulders, ankles and elbows that have deteriorated as a result of disease or injury. Trauma implant systems are used primarily to reattach or stabilize damaged bone or tissue while the body heals. Spinal implant systems are used by orthopaedic surgeons and neurosurgeons in the treatment of degenerative diseases, deformities and injuries in various regions of the spine.

Each implant system typically has an associated instrument set that is used in the surgical procedure to insert that specific implant system. Instruments included in a set vary by implant system. Usually, instrument sets are sterilized after each use and then reused, however, recent trends are moving towards disposable instrumentation, which the Company is positing itself to take advantage of. Cases are used to store, transport and arrange implant systems and other medical devices and related surgical instruments. Cases are generally designed to allow for sterilization and re-use after an implant or other surgical procedure is performed. The majority of cases are tailored for specific implant procedures so that the instruments, implants and other devices are arranged within the case to match the order of use in the procedure and are securely held in clearly labeled, custom-formed pockets.

Many of the factors affecting the orthopaedic market segment are similar to the CRM and Vascular Access markets. These factors include aging population, new implant and surgical technology, rising rates of obesity, a growing replacements market and emerging affluence in developing nations. As a result, we believe that the orthopaedic market has strong growth fundamentals.

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The following table summarizes information about our Greatbatch Medical products:

PRODUCT	DESCRIPTION	PRINCIPAL PRODUCT ATTRIBUTES
Batteries	Power sources include: Lithium iodine (Li Iodine) Lithium silver vanadium oxide (Li SVO) Lithium carbon monoflouride (Li CFx) Lithium ion rechargeable (Li Ion) Lithium SVO/CFx (HQ & MQ)	High reliability and predictability Long service life Customized configuration Light weight Compact and less intrusive
Capacitors	Storage for energy generated by a battery before delivery to the heart. Used in ICDs and CRT-Ds.	Stores more energy per unit volume (energy density) than other existing technologies Customized configuration
EMI filters	Filters electromagnetic interference to limit undesirable response, malfunctioning or degradation in the performance of electronic equipment	High reliability attenuation of EMI RF over wide frequency ranges Customized design
Feedthroughs	Allow electrical signals to be brought from inside hermetically sealed IMD to an electrode	Ceramic to metal seal is substantially more durable than traditional seals Multifunctional
Coated electrodes	Deliver electric signal from the feedthrough to a body part undergoing stimulation	High quality coated surface Flexible in utilizing any combination of biocompatible coating surfaces Customized offering of surfaces and tips
Precision components	Machined Molded and over molded products	High level of manufacturing precision Broad manufacturing flexibility
Enclosures and related components	Titanium Stainless steel	Precision manufacturing, flexibility in configurations and materials
Value-added assemblies	Combination of multiple components in a single package/unit	Leveraging products and capabilities to provide subassemblies and assemblies Provides synergies in component technology and procurement systems
Leads	Cardiac, neuro and hearing restoration stimulation leads	Custom and unique configurations that increase therapy effectiveness, provide finished device design and manufacturing
Introducers	Creates a conduit to insert infusion catheters, guidewires, implantable ports, pacemaker leads and other therapeutic devices into a blood vessel	Variety of sizes and materials that facilitate problem-free access in a variety of clinical applications

Catheters	Delivers therapeutic devices to specific sites in the body	Enable safe, simple delivery of therapeutic and diagnostic devices, soft tip and steerability. Provide regulatory clearance and finished device
Trays	Delivery systems for cleaning and sterilizing orthopaedic instruments and implants	Deliver turn-key full service kits
Implants	Orthopaedic implants for reconstructive hip, knee, shoulder, trauma and spine procedures	Precision manufacturing, leveraging capabilities and products, complete processes including sterile packaging and coatings
Instruments	Orthopaedic instruments for reconstructive and trauma procedures	Designed to improve surgical techniques, reduce surgery time, increase surgical precision and decrease risk of contamination
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A majority of the products Greatbatch Medical sells incorporate proprietary technologies. These proprietary technologies provide an entry barrier for new competitors, and further limit existing competitors from duplicating our products. In addition to these proprietary technologies, our proprietary know-how in the manufacture of these products provides further barriers to our competition.

ELECTROCHEM

Our customized rechargeable and non-rechargeable battery solutions are used in a number of demanding industrial markets such as energy, security, portable medical, environmental monitoring and more. Applications in these segments cover a number of battery-powered systems including downhole drilling tools, hand-held military communications, automated external defibrillators, and more. Electrochem s primary and non-rechargeable power and Wireless Sensing solutions are used in these core markets because of extreme operating conditions and long life requirements.

Our primary batteries operate reliably and safely at extremely high and low temperatures and with high shock and vibration. The product designs incorporate protective circuitry; glass-to-metal hermetic seals, fuses and diodes help ensure safe, reliable power as devices are subjected to harsh conditions.

Our secondary, or rechargeable, power solutions include a number of chemistries including lithium, nickel and lead acid, and incorporate advanced electronics, monitoring and security features and other capabilities. We provide value-added solutions to complement our secondary power systems such as charging and battery management. Electrochem s unique Wireless Sensing Systems are a complete solution, incorporating advanced, ruggedized sensors, intelligent gateways and customized software. Electrochem s patented system utilizes our own batteries and offers control and monitoring for applications in existing markets such as energy, and new markets such as food and beverage and water/wastewater process control.

The following table summarizes information about our Electrochem products:

PRODUCT	DESCRIPTION	PRINCIPAL PRODUCT ATTRIBUTES
Cells	Moderate-rate Spiral (high rate)	Optimized rate capability, shock and vibration resistant, high and low temperature tolerant High energy density
Primary and rechargeable battery packs	Packaging of commercial batteries in a customer specific configuration	Increased power and recharging capabilities and ease of integration into customer applications
Wireless sensors	Operates where wired sensors are undesirable or impractical	Measures pressure, temperature and flow; withstands harsh environments

RESEARCH AND DEVELOPMENT

Our position as a leading developer and manufacturer of components for IMDs and Electrochem batteries is largely the result of our long history of technological innovation. We invest substantial resources in research, development and engineering. Our scientists, engineers and technicians focus on improving existing products, expanding the use of our products and developing new products. In addition to our internal technology and product development efforts, we also engage outside research institutions for unique technology projects.

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In 2009, the Company formed the QiG Group LLC (QiG). QIG facilitates the introduction of new and improved technologies in medical device markets by investing in the development of innovations. This includes passive investments in startup companies as well as long-term systems level projects, which augment the Company s Greatbatch Medical business. These investments support the development of ideas and technologies that can be used to better serve our OEM customers and typically have longer development times than our core Greatbatch Medical products.

PATENTS AND PROPRIETARY TECHNOLOGY

We rely on a combination of patents, licenses, trade secrets and know-how to establish and protect our proprietary rights to our technologies and products. We have 396 active U.S. patents and 295 active foreign patents. We also have 247 U.S. and 455 foreign pending patent applications at various stages of approval. During the past three years, we have been granted 63 new U.S. patents, of which 29 were granted in 2009. Corresponding foreign patents have been issued or are expected to be issued in the near future. Often, several patents covering various aspects of the design protect a single product. We believe this provides broad protection of the inventions employed.

We are also a party to several license agreements with third parties under which we have obtained, on varying terms, exclusive or non-exclusive rights to patents held by them. An example of these agreements is for the basic technology used in our wet tantalum capacitors, filtered feedthroughs and MRI compatible lead systems. We have also granted rights in our patents to others under license agreements.

It is our policy to require our management and technical employees, consultants and other parties having access to our confidential information to execute confidentiality agreements. These agreements prohibit disclosure of confidential information to third parties except in specified circumstances. In the case of employees and consultants, the agreements generally provide that all confidential information relating to our business is the exclusive property of the Company.

MANUFACTURING AND QUALITY CONTROL

While we have adequate capacity, we primarily manufacture small lot sizes, as most customer orders range from a few hundred to a few thousand units. As a result, our ability to remain flexible is an important factor in maintaining high levels of productivity. Each of our production teams receives assistance from a manufacturing support team, which typically consists of representatives from our quality control, engineering, manufacturing, materials and procurement departments. Our quality systems are compliant with and certified to various recognized international standards. Our facilities in Raynham, MA, Alden, NY, Clarence, NY, and Minneapolis, MN are ISO-9001 registered, which requires compliance with regulations regarding quality systems of product design (where applicable), supplier control, manufacturing processes and management review. This certification can only be achieved after completion of an audit conducted by an independent authority.

The Quality Systems of our manufacturing facilities in Tijuana, Mexico, Plymouth, MN, Clarence, NY, Chaumont, France, Orvin, Switzerland, Columbia City, IN and Indianapolis, IN sites are certified to the requirements of ISO-13485(2003) for the design (where applicable) and manufacture of components, assemblies and finished medical devices. Along with ISO 13485: 2003, the facilities (where applicable) meet individual country and registration requirements in order to ship product worldwide. This certification gives us the ability to serve as a manufacturing partner to medical device manufacturers, which we believe will improve our competitive position in the Vascular Access, CRM and emerging Neuromodulation and Orthopaedic markets. Our Plymouth, MN and all Orthopaedic facilities are also registered with the FDA, thus enabling the manufacture and distribution of FDA cleared medical devices within the U.S.

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Our existing manufacturing plants are audited by several notified bodies (TUV, G-Med, QMI, BSI, and the National Standards Authority of Ireland). To maintain certification, all facilities must be reexamined routinely by their respective notified body.

SALES AND MARKETING

Products from our Greatbatch Medical business are sold directly to our customers. In our Electrochem business, we utilize a combination of direct and indirect sales methods, depending on the particular product. In 2009, approximately 47% of our products were sold in the U.S. Sales outside the U.S. are primarily to customers whose corporate offices are located and headquartered in the U.S. Information regarding our sales by geographic area is set forth at Note 13 Business Segment Information of the Notes to Consolidated Financial Statements contained at Item 8 of this report. Although the majority of our medical customers contract with us to develop custom components and assemblies to fit their product specifications, we also provide system level solutions ready for market distribution by OEM s. As a result, we have established close working relationships between our internal program managers and our customers. We market our products and technologies at industry meetings and trade shows domestically and internationally. Internal sales managers support all activity and involve engineers and technology professionals in the sales process to address customer requests appropriately. For system level solutions we partner with our customers Research, Marketing, and Clinical groups to jointly develop technology platforms in alignment with their product roadmaps and therapy needs.

We sell our Electrochem cells and battery packs directly to the end user, directly to manufacturers that incorporate our products into other devices for resale, and to distributors who sell our products to manufacturers and end users. Our sales managers are trained to assist our customers in selecting appropriate chemistries and configurations. We market our Electrochem products at various technical trade meetings, conferences and shows. We also place advertisements in relevant trade publications and on the Internet.

Firm backlog orders at January 1, 2010 and January 2, 2009 were approximately \$178.2 million and \$190.4 million, respectively. Most of these orders are expected to be shipped within one year. See Customers section below for further discussion.

CUSTOMERS

Our Greatbatch Medical customers include large multi-national OEMs and their affiliated subsidiaries such as, in alphabetical order here and throughout this report, Biotronik, Boston Scientific, DePuy, Johnson & Johnson, Medtronic, Smith & Nephew, Sorin Group, St. Jude Medical, Stryker and Zimmer. During 2009 and 2008, Boston Scientific, Johnson & Johnson, Medtronic and St. Jude Medical collectively accounted for 63% and 56% of our total sales, respectively.

The nature and extent of our selling relationship with each OEM customer is different in terms of products purchased, selling prices, product volumes, ordering patterns and inventory management. For customers with long-term contracts, we have negotiated fixed pricing arrangements for pre-determined volume levels with pricing fixed within each level. In general, the higher the volume level, the lower the pricing. We have pricing arrangements with our customers that at times do not specify minimum order quantities. We recognize revenue when it is realized or realizable and earned. This occurs when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, the buyer is obligated to pay us (i.e., not contingent on a future event), the risk of loss is transferred, there is no obligation of future performance, collectability is reasonably assured and the amount of future returns can reasonably be estimated. Those criteria are met at the time of shipment when title passes.

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Our visibility to customer ordering patterns is over a relatively short period of time. Our customers may have inventory management programs and alternate supply arrangements of which we are unaware. Additionally, the relative market share among the OEM manufacturers changes periodically. Consequently, these and other factors can significantly impact our sales in any given period. Our customers may initiate field actions with respect to market-released products. These actions may include product recalls or communications with a significant number of physicians about a product or labeling issue. The scope of such actions can range from very minor issues affecting a small number of units to more significant actions. There are a number of factors, both short-term and long-term, related to these field actions that may impact our results. In the short-term, if a product has to be replaced, or customer inventory levels have to be restored, demand will increase. Also, changing customer order patterns due to market share shifts or accelerated device replacements may also have a positive or negative impact on our sales results in the near-term. These same factors may have longer-term implications as well. Customer inventory levels may ultimately have to be rebalanced to match new demand.

The initial term of our supply agreement with Boston Scientific pursuant to which Boston Scientific purchases a certain percentage of the batteries, capacitors, filtered feedthroughs and case halves it uses in its IMDs ends on December 31, 2010. The agreement may be renewed for one or more four-year renewal terms upon mutual agreement of the parties. We are actively negotiating a follow-on agreement with targeted completion during 2010. Our Electrochem customers are primarily companies involved in demanding applications in markets such as energy, security, portable medical and environmental monitoring including Halliburton Company, Weatherford International, General Electric, Thales, Zoll Medical Corp. and Scripps Institution of Oceanography.

SUPPLIERS AND RAW MATERIALS

We purchase certain critical raw materials from a limited number of suppliers due to the technically challenging requirements of the supplied product and/or the lengthy process required to qualify these materials with our customers. We cannot quickly establish additional or replacement suppliers for these materials because of these requirements. In the past, we have not experienced any significant interruptions or delays in obtaining these raw materials. We maintain minimum safety stock levels of critical raw materials.

For other raw material purchases, we utilize competitive pricing methods such as bulk purchases, precious metal pool buys, blanket orders, and long-term contracts to secure supply. We believe that there are alternative suppliers or substitute products available at competitive prices for all of the materials we purchase.

COMPETITION

Existing and potential competitors in our Greatbatch Medical business include leading IMD manufacturers such as Biotronik, Boston Scientific, DePuy, Johnson & Johnson, Medtronic, Smith & Nephew, Sorin Group, St. Jude Medical, Stryker and Zimmer that currently have vertically integrated operations and may expand their vertical integration capability in the future. Competitors also include independent suppliers who typically specialize in one type of component.

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Our known non-vertically integrated competitors include the following:

Product Line Competitors

Medical batteries Litronik (a subsidiary of Biotronik)

Eagle-Picher

Capacitors Critical Medical Components

Feedthroughs Alberox (subsidiary of The Morgan Crucible Co. PLC)

EMI filtering AVX (subsidiary of Kyocera)

Eurofarad

Enclosures Heraeus

Hudson

Machined and molded components Numerous

Value added assembly Numerous

Catheters Teleflex

Leads Oscor

Orthopaedic trays, instruments and Symmetry

implants Paragon

Accelent Teleflex Viasys Orchid

GOVERNMENT REGULATION

Except as described below, our business is not subject to direct governmental regulation other than the laws and regulations generally applicable to businesses in the jurisdictions in which we operate. We are subject to federal, state and local environmental laws and regulations governing the emission, discharge, use, storage and disposal of hazardous materials and the remediation of contamination associated with the release of these materials at our facilities and at off-site disposal locations. Our manufacturing and research, development and engineering activities may involve the controlled use of small amounts of hazardous materials. Liabilities associated with hazardous material releases arise principally under the federal Comprehensive Environmental Response, Compensation and Liability Act and analogous state laws that impose strict, joint and several liability on owners and operators of contaminated facilities and parties that arrange for the off-site disposal of hazardous materials. We are not aware of any material noncompliance with the environmental laws currently applicable to our business and we are not subject to any material claim for liability with respect to contamination at any Company facility or any off-site location. We cannot assure you that we will not become subject to such environmental liabilities in the future as a result of historic or current operations.

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To varying degrees, our products are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. The medical product components we manufacture are not subject to regulation by the FDA. We have master files on record with the FDA. Master files may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging and storing of one or more medical device components. These submissions may be used by device manufacturers to support the premarket notification process required by Section 510(k) of the Federal Food Drug & Cosmetic Act. This notification process is necessary to obtain clearance from the FDA to market a device for human use in the U.S.

The medical devices we manufacture and market are subject to regulation by the FDA and, in some instances, by state and foreign authorities. Pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and related regulations, medical devices intended for human use are classified into three categories (Classes I, II and III), depending upon the degree of regulatory control to which they will be subject.

In the U.S., our introducer and delivery catheter products are considered Class II devices. If a Class II device is substantially equivalent to an existing (predicate) device that has been continuously marketed since the effective date of the 1976 Amendments, FDA requirements may be satisfied through a Pre-market Notification Submission or 510(k) submission under which the applicant provides product information supporting its claim of substantial equivalence. In a 510(k) Submission, the FDA may also require that we provide clinical test results demonstrating the safety and efficacy of the device.

Generally, Class III devices are typically life-sustaining, life supporting, or implantable devices that must receive Pre-Market Approval (PMA) by the FDA to ensure their safety and effectiveness. A PMA is a more rigorous approval process typically requiring human clinical studies. Certain leads that we manufacture and market are Class III devices, but any required PMA is submitted by and issued to our customers.

As a manufacturer of medical devices, we are also subject to certain other FDA regulations and our device manufacturing processes and facilities are subject to on-going review by the FDA in order to ensure compliance with the current Good Manufacturing Practices Regulation (21 CFR 820). We believe that our manufacturing and quality and regulatory systems conform to the requirements of all pertinent FDA regulations. Our sales and marketing practices are subject to regulation by the U.S. Department of Health and Human Services pursuant to federal anti-kickback laws, and are also subject to similar state laws.

We are also subject to various other environmental, transportation and labor laws as well as various other directives and regulations both in the U.S. and abroad. We believe that compliance with these laws will not have a material impact on our capital expenditures, earnings or competitive position. Given the scope and nature of these laws, however, there can be no assurance that they will not have a material impact on our results of operations. We assess potential product related liabilities on a quarterly basis. At present, we are not aware of any such liabilities that would have a material impact on our business.

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RECRUITING AND TRAINING

We invest substantial resources in our recruiting efforts that focus on supplying quality personnel to support our business objectives. We have established a number of programs that are designed to challenge and motivate our employees. All staff are encouraged to be proactive in contributing ideas. Feedback surveys are used to collect suggestions on ways that our business and operations can be improved. Our goal is to fill any open employment positions internally. We further meet our hiring needs through outside sources as required. We have a comprehensive succession program in place for senior management in order to ensure we will be able to implement our strategic plan. We provide a training program for our new employees that is designed to educate them on safety, quality, business strategy, corporate culture, and the methodologies and technical competencies that are required for our business. Our safety training programs focus on such areas as basic industrial safety practices and emergency response procedures to deal with any potential fires or chemical spills. All of our employees are required to participate in a specialized training program that is designed to provide an understanding of our quality objectives. Supporting our lifelong learning environment, we offer our employees a tuition reimbursement program and encourage them to continue their education at accredited colleges and universities. Many of our employees attend seminars on topics that are related to our corporate objectives and strategies. We believe that comprehensive training is necessary to ensure that our employees have state of the art skills, utilize best practices, and have a common understanding of work practices.

EMPLOYEES

The following table provides a breakdown of employees as of January 1, 2010:

Manufacturing	1,442
General and administrative	126
Sales and marketing	52
Research, development and engineering	197
Chaumont, France facility	214
Switzerland facilities	214
Tijuana, Mexico facility	816
Total	3,061

We also employ a number of temporary employees to assist us with various projects and service functions and address peaks in staff requirements. Our employees at our Chaumont, France and Tijuana, Mexico facilities are represented by a union. Approximately 159 and 196 positions at our Switzerland and France locations, respectively, are manufacturing in nature. The positions at our Tijuana, Mexico facility are primarily manufacturing. We believe that we have a good relationship with our employees.

EXECUTIVE OFFICERS OF THE COMPANY

Information concerning our executive officers is presented below as of March 2, 2010. The officers terms of office run until the first meeting of the Board of Directors after our Annual Meeting, which takes place immediately following our Annual Meeting of Stockholders and until their successors are elected and qualified, except in the case of earlier death, retirement, resignation or removal.

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Mauricio Arellano, age 43, is Senior Vice President and the Business Leader for our Cardiac and Neurology Group and has served in that office since October 2008. He served as the Senior Vice President and Business Leader of our CRM and Neuromodulation Group from January 2008 to October 2008, our Medical Solutions Group from November 2006 to January 2008 and as Vice President of Greatbatch Mexico from January 2005 to November 2006. Mr. Arellano joined our Company in October 2003 as the Plant Manager of our former Carson City, NV facility. Prior to joining our Company, he served in a variety of human resources and operational roles with Tyco Healthcare Especialidades Medicas Kenmex and with Sony de Tijuana Este.

Susan M. Bratton, age 53, is Senior Vice President and Business Leader for our Electrochem business and has served in that office since January 2005. She served as Vice President of Corporate Quality from March 2001 to January 2005, as General Manager of our Electrochem Division from July 1998 to March 2001 and as Director of Procurement from June 1991 to July 1998. Ms. Bratton has held various other positions with our Company since joining us in 1976.

Susan H. Campbell, age 45, is Senior Vice President and the Business Leader for our Orthopaedics Group and has served in that office since October 2008. Ms. Campbell had served as Senior Vice President for Global Manufacturing and Supply Chain from January 2008 until October 2008 and the Business Leader for our Medical Power Group from January 2005 until January 2008. She joined our Company in April 2003 as the Plant Manager for our medical battery facility. Prior to that time, Ms. Campbell was a plant manager for Delphi Corporation and General Motors Corporation.

Barbara M. Davis, age 59, is Vice President for Human Resources, and has served in that office since April 2004. She joined our Company in October 1998 as Director of Human Resources and Organization Development. **Thomas J. Hook,** age 47, has served as our President & Chief Executive Officer since August 2006. Prior to August 2006, he was our Chief Operating Officer, a position he assumed upon joining our Company in September 2004. From August 2002 until September 2004, Mr. Hook was employed by CTI Molecular Imaging where he had served as President, CTI Solutions Group.

Thomas J. Mazza, age 56, is Senior Vice President & Chief Financial Officer, and has served in that office since August 2005. He joined our Company in November 2003 as Vice President and Corporate Controller. Prior to that, Mr. Mazza served in a variety of financial roles with Foster Wheeler Ltd., including Vice President and Corporate Controller.

Timothy G. McEvoy, age 52, is Vice President, General Counsel & Secretary, and has served in that office since joining our Company in February 2007. From 1992 until January 2007, he was employed in a variety of legal roles by Manufacturers and Traders Trust Company, most recently as Administrative Vice President and Deputy General Counsel.

AVAILABLE INFORMATION

We make available free of charge through our Internet website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission. Our Internet address is www.greatbatch.com. The information contained on our website is not incorporated by reference in this annual report on Form 10-K and should not be considered a part of this report. These items may also be obtained free of charge by written request made to Christopher J. Thome, Manager of External Reporting and Investor Relations, Greatbatch, Inc., 10000 Wehrle Drive, Clarence, New York 14031.

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CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

Some of the statements contained in this annual report on Form 10-K and other written and oral statements made from time to time by us and our representatives, are not statements of historical or current fact. As such, they are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations, which are subject to known and unknown risks, uncertainties and assumptions. They include statements relating to:

future sales, expenses and profitability;

the future development and expected growth of our business and industry;

our ability to execute our business model and our business strategy;

our ability to identify trends within our industries and to offer products and services that meet the changing needs of those markets; and

intends

projected capital expenditures.

You can identify forward-looking statements by terminology such as may, will, should, could, believes. estimates. predicts, potential or continue or the negative of these terms or other compara anticipates. terminology. These statements are only predictions. Actual events or results may differ materially from those stated or implied by these forward-looking statements. In evaluating these statements and our prospects generally, you should carefully consider the factors set forth below. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary factors and to others contained throughout this report. We are under no duty to update any of the forward-looking statements after the date of this report or to conform these statements to actual results.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from the results expressed or implied by our forward-looking statements or that may affect our future results, some of these factors include the following: dependence upon a limited number of customers; customer ordering patterns; product obsolescence; our inability to market current or future products; pricing pressure from customers; our ability to timely and successfully implement our cost reduction and plant consolidation initiatives; our reliance on third party suppliers for raw materials, products and subcomponents; fluctuating operating results; our inability to maintain high quality standards for our products; challenges to our intellectual property rights; product liability claims; our inability to successfully consummate and integrate acquisitions and to realize synergies and to operate these acquired businesses in accordance with expectations; our unsuccessful expansion into new markets; our inability to obtain licenses to key technology; regulatory changes or consolidation in the healthcare industry; global economic factors including currency exchange rates and interest rates; the resolution of various legal actions brought against the Company; and other risks and uncertainties that arise from time to time and are described in Item 1A Risk Factors of this report.

ITEM 1A. RISK FACTORS

Our business faces many risks. Any of the risks discussed below, or elsewhere in this report or in our other SEC filings, could have a material impact on our business, financial condition or results of operations. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also impair our business operations.

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Risks Related To Our Business

We depend heavily on a limited number of customers, and if we lose any of them or they reduce their business with us, we would lose a substantial portion of our revenues.

In 2009, Boston Scientific, Johnson & Johnson, Medtronic and St. Jude Medical, collectively accounted for approximately 63% of our revenues. Our supply agreements with these customers might not be renewed. Furthermore, many of our supply agreements do not contain minimum purchase level requirements and therefore there is no guaranteed source of revenue that we can depend upon under these agreements. The loss of any large customer or a reduction of business with that customer for any reason would harm our business, financial condition and results of operations.

If we do not respond to changes in technology, our products may become obsolete and we may experience a loss of customers and lower revenues.

We sell our products to customers in several industries that are characterized by rapid technological changes, frequent new product introductions and evolving industry standards. Without the timely introduction of new products and enhancements, our products and services will likely become technologically obsolete over time and we may lose a significant number of our customers. In addition, other new products introduced by our customers may require fewer of our components. We dedicate a significant amount of resources to the development of our products and technologies and we would be harmed if we did not meet customer requirements and expectations. Our inability, for technological or other reasons, to successfully develop and introduce new and innovative products could result in a loss of customers and lower revenues.

If we are unable to successfully market our current or future products, our business will be harmed and our revenues and operating results will be reduced.

The market for our medical and commercial products has been growing in recent years. If the market for our products does not grow as rapidly as forecasted by industry experts, our revenues could be less than expected. In addition, it is difficult to predict the rate at which the market for our products will grow or at which new and increased competition will result in market saturation. Slower growth in the CRM, Orthopaedic, Vascular Access or Energy markets in particular would negatively impact our revenues. In addition, we face the risk that our products will lose widespread market acceptance. Our customers may not continue to utilize the products we offer and a market may not develop for our future products.

We may at times determine that it is not technically or economically feasible for us to continue to manufacture certain products and we may not be successful in developing or marketing them. Additionally, new technologies that we develop may not be rapidly accepted because of industry-specific factors, including the need for regulatory clearance, entrenched patterns of clinical practice and uncertainty over third party reimbursement. If this occurs, our business will be harmed and our operating results will be negatively affected.

We are subject to pricing pressures from customers, which could harm operating results.

We have made price reductions to some of our large customers in recent years and we expect customer pressure for price reductions will continue. Price concessions or reductions may cause our operating results to suffer. In addition, any delay or failure by a large customer to make payments due to us would harm our operating results and financial condition.

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