510(k) Summary
Cerclage System

JUL 3 2012

510(k) Number: K120177

Manufacturer Identification

Submitted by:
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Date Prepared: December 14, 2011

Device Indentification

Proprietary Name Spinal Elements Cerclage System

Common Name Cerclage

Device Classification 21 CFR 888.3010

Classification Name: Bone Fixation, Cerclage

Proposed Regulatory Class Class II

Device Product Code: JDQ

Purpose of this 510(k)
This 510(k) seeks clearance for a new system.

Device Description
The Spinal Elements Cerclage System consists of a strap manufactured from PEEK-Optima®. The leading tip of the device is tapered and smooth to help lead the cerclage through or around the bony structures to be secured. The device has teeth along its length that interact with a latching mechanism at the opposite end of the strap. The latch allows a loop, created by feeding the strap though the latch, to be made consecutively shorter or

taught by continuing to pull the strap through the latch. The latch resists the lengthening of the loop due to forces that would pull the strap in the opposite direction, thereby securing the structures intended to be fixed. Once the desired loop length is reached, the unneeded portion of the strap may be cut off and discarded.

Intended Use of the Device

The Spinal Elements Cerclage System is intended for use in cardiovascular surgery. The indications for use include cardiovascular surgery for closure of the sternum following sternotomy. The system is intended to provide temporary stabilization during the development of solid bony fusion.

Performance Data

Non-clinical, mechanical testing was performed to determine the performance profile of the device. Testing included:

- Static tensile testing
- Dynamic tensile testing
- Relative abrasion testing
- Creep tensile testing

All test results indicate the cerclage will perform as intended based on a comparison to devices cleared for similar or identical indications for use.

Substantial Equivalence

Spinal Elements Cerclage system is substantially equivalent to the following predicate devices:

- Ethicon Stainless Steel Suture Wire (K931271 and K946173)
- Synthes Sternal ZipFix System (K110789)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spinal Elements, Inc.
% Mr. Benjamin A. Kimball
Regulatory Affairs Manager
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

JUL 3 2012

Re: K120177
Trade/Device Name: Spinal Elements Cerclage System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: June 18, 2012
Received: June 22, 2012

Dear Mr. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k): K120177

Device Name: Spinal Elements Cerclage System

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120177