JUL 28 2011

3.0 510(k) Summary

Date Prepared	May 24, 2011
Submitter	SYNTHES (USA) 1301 Goshen Parkway West Chester, PA 19380 United States of America
Contact	Andrea M. Tasker tasker.andrea@synthes.com phone: (610) 719-6290
Trade Name	Synthes Sternal ZipFix™ System
Common Name	cerclage, fixation
Regulation Name	Bone Fixation Cerclage
Regulation Number	21 CFR §888.3010
Device Class	2
Review Panel	Orthopedic
Product Codes	Primary: JDQ
Predicate Devices	K931271- Ethicon Stainless Steel Suture Wire K946173- Ethicon Stainless Steel Suture Wire K093772 - Synthes Sternal Fixation System
Device Description	The Synthes Sternal ZipFix™ System consists of polyetheretherketone (PEEK Optima LT-3) cable ties with detachable, stainless steel needle. The ZipFix are placed in peristernal fashion through the intercostal space, with the help of the detachable needle. Once inserted, the needle is removed and the ZipFix™ are tightened and secured in place to provide stable fixation of the sternum. The ZipFix™ can be cut and removed for emergent, and long-term, re-entry through the sternum.
Intended Use	The Synthes Sternal ZipFix™ System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Technological Characteristics	The Synthes ZipFix™ Sternal System is similar to the predicate devices in terms of intended use, principles of operation and mechanical performance. The Synthes ZipFix™ Sternal System has the same intended use as K093772 - Synthes Sternal Fixation System. The Synthes ZipFix™ Sternal System has the same principles of operation as K931271/ K946173- Ethicon Stainless Steel Suture Wire in that they placed in peristernal fashion through the intercostal space, with the help of the detachable needle and tightened and secured to provide stable fixation of the sternum. The Synthes ZipFix™ Sternal System has had equivalent or better performance compared to K931271/ K946173- Ethicon Stainless Steel Suture Wire with respect to static loading strength and stiffness, fatigue strength, resistance to cut-through, and construct strength.
Clinical Testing Data	No clinical testing was performed to support this submission.
Non-Clinical Testing Data	Mechanical testing was performed to compare the Synthes ZipFix™ Sternal Fixation System to the predicated device, stainless steel surgical wire, for sternal closure. The Sternal ZipFix™ and stainless steel wire were compared based on single implant static and dynamic tests and cut through resistance testing. Based on a worst case construct, simulated-use construct testing was also performed compared to the predicate. Needle pull-out force testing was performed on the Sternal ZipFix™ device to determine the amount of force required to remove the needle from the implant. Creep testing was performed on the Sternal ZipFix™ device to determine the amount of deformation when held under a constant load. The ZipFix™ application instrument was tested for tensioning performance and life cycle testing. The mechanical testing showed that Sternal ZipFix™ had equivalent or better performance compared to stainless steel surgical wire with respect to static loading strength and stiffness, fatigue strength, resistance to cut-through, and construct strength. The Sternal ZipFix™ passed the mechanical test acceptance criteria for needle pull out and creep testing. The ZipFix™ application instrument passed the mechanical testing acceptance criteria for tensioning performance and life cycle testing. The new Synthes Sternal ZipFix™ System implants are manufactured from (PEEK Optima LT-3). This material has a well-established biocompatibility history. According to the results of biocompatibility testing on the finished device, the biocompatibility requirements have been met. Cytotoxicity testing was also performed on the finished device after sterilization. The finished product was determined to be non-cytotoxic.

Substantial Equivalence to Predicate Devices	In conclusion, the Synthes Sternal ZipFix™ System has similar intended use, principles of operation, mechanical performance compared to the predicate device. Non-clinical testing data demonstrate that differences in design and material do not raise new issues of safety or effectiveness. The information presented supports substantial equivalence of the Synthes Sternal ZipFix™ Sternal System to the predicate devices.

(end of summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Synthes (USA)
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JUL 28 2011

Re: K110789
Trade/Device Name: Synthes Sternal ZipFix™ System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: July15, 2011
Received: July 18, 2011

Dear Ms. Tasker:

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

2.0 **Indications for Use**

510(k) Number (if known): K110789

Device Name: Synthes Sternal ZipFix™ System

Indications for Use: The Synthes Sternal ZipFix™ System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

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

510(k) Number K110789