SYNTHES®

510(k) Summary

Date Prepared: 09/15/2010

Sponsor:
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SEP 15 2010

Contact:
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Device Name: 2.7/3.5mm VA-LCP Anterior Clavicle Plate System

Classification: Class II. §888.3030 - Single/multiple component metallic bone fixation appliances and accessories

Predicate Device: Synthes 3.5mm LCP Reconstruction Plate System, *K000684*
Synthes 3.5mm LCP Superior Anterior Clavicle Plate System, *K073186*

Device Description: The Synthes 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle Plate System consists of plates of various lengths and variable angle screws that provide the flexibility to lock screws in trajectories that can diverge from the central axis of the plate hole.

The system features medial and lateral plates that are precontoured to match the anatomy of the clavicle and a limited contact, low profile design. The plate with lateral extension features Variable Angle (VA) Locking holes and Dynamic Compression Plate (DCP) holes. The medial plate features Dynamic Compression Plate (DCP) holes combined with VA locking screw holes.

Indications for Use: The Synthes 2.7 mm/ 3.5 mm VA-LCP Anterior Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

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510(k) Summary (continued)

Substantial Equivalence:

Comparison of design characteristics, test results, and engineering analysis supports substantial equivalence of the Synthes 2.7/3.5mm VA-LCP Anterior Clavicle plate System to the predicate devices stated.

- Indications for Use- are the same except that a pediatric indication has been added to the proposed plate.
- Technological Characteristics- The predicate systems and the proposed systems:
  - Are machined metal plates made from the same alloys.
  - Are pre-contoured for the clavicle.
  - Incorporate combination dynamic compression/threaded locking screw holes.
  - Have similar geometric dimensions- thickness, shaft width, overall length, and number of screw holes.
  - Have limited contact designs for minimization of vascular trauma.
  - Allow additional contouring.
  - Allow the same size cortex, locking cortex, and cancellous screws.

- Testing/Engineering Analysis:
  - Static Compression ultimate load strength testing showed that the proposed plate system (plate/screw construct) has a much higher bending strength than that of the of the predicate plate systems.
  - Engineering Calculations confirms that the bending strength of the proposed plate system is greater than the bending strength of the predicate plate system.

Based on these results, the proposed 2.7/3.5 mm VA-LCP Anterior Clavicle plate system presents no new issues of safety or effectiveness.

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

Synthes (USA)
% Ms. Lisa Graney
1301 Goshen Parkway
West Chester, Pennsylvania 19380

SEP 1 6 2010

Re: K101536
Trade/Device Name: 2.7/3.5mm VA-LCP Anterior Clavicle Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and appliances
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 16, 2010
Received: August 16, 2010

Dear Ms. Graney:

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

SYNTHES®

2.0 **Indications for Use**

SEP 15 2010

510(k) Number (if known): K101536

Device Name: **2.7/3.5mm VA-LCP Anterior Clavicle Plate System**

Indications for Use: The Synthes 2.7 mm/ 3.5 mm VA-LCP Anterior Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

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

Joanne C. for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101536