SYNTHES®

K060138

JUN - 2 2006

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Device Name: Synthes Craniomaxillofacial (CMF) Distraction System

Classification: Class II, §872.4760 – External mandibular fixation and/or distractor.

Predicate Devices: KLS Martin – Zurich Distraction System
KLS Martin – Micro Zurich Distractor

Device Description: The Synthes Craniomaxillofacial Distraction System, which includes the Pediatric CMF Distraction System, is a modular family of internal distraction osteogenesis devices that are used to gradually lengthen the mandible body and ramus. Each device, when assembled, is comprised of a distractor body, two footplates, and a machine screw to secure the assembly. The system also includes optional activation arms, which can be attached to the activation end of the device to move the point of activation to an area accessible by the activation instrument.

Intended Use: The Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The Synthes CMF Distraction System is intended for single use only.

The Synthes Pediatric CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required in children under the age of 12 months. The Synthes Pediatric CMF Distraction System is intended for single use only.

Substantial Equivalence: Documentation is provided which demonstrates the Synthes CMF Distraction System to be substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Ms. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
Synthes (USA)
1301 Goshen Park Way
West Chester, Pennsylvania 19380

Re: K060138
Trade/Device Name: Synthes (USA) Craniomaxillofacial Distraction System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: May 19, 2006
Received: May 22, 2006

Dear Ms. Musgnung:

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.

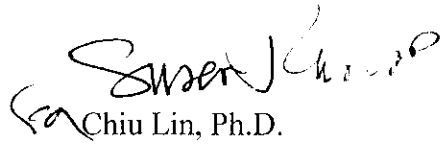
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

K060138

2.0 Indications for Use

510(k) Number (if known): _____

Device Name: Synthes (USA) Craniomaxillofacial Distraction System

INDICATIONS FOR USE:

The Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The Synthes CMF Distraction System is intended for single use only.

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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)

...on Sign-Off)
...ent of Anesthesiology, General Hospital,
...tion Control, Dental Devices

K060138