

K050378

3.0 510(k) Summary

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Sponsor: Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

MAR 15 2005

Device Name: Synthes Mandible External Fixator

Classification: Class II, 21 CFR §872.4760
Bone Plate

Predicate Device: Synthes Mandible External Fixator

Device Description: Synthes Mandible External Fixator consists of the following components: An adjustable parallel pin clamp – MR safe; 4.0/2.5 Schanz Screws, 2.0 mm K-wires; and 4.0 mm Titanium Rods. The components of this system are designed for use in the MR environment. The rods and Schanz Screws are available in various lengths.

Intended Use: Synthes Mandible External Fixator is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Substantial Equivalence: Documentation is provided which demonstrates that Synthes Mandible External Fixator is substantially equivalent to other legally marketed Synthes devices.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

MAR 15 2005

Re: K050378
Trade/Device Name: Synthes Mandible External Fixator
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: February 14, 2005
Received: February 15, 2005

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



Indications for Use

510(k) Number (if known): K050378

Device Name: Synthes Mandible External Fixator

Indications: Synthes Mandible External Fixator is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 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)

(Print Name)
Susan D. [unclear]
Department of Anesthesiology, General Hospital
FDA Region Control, Dental Devices

510(k) Number: K050378

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