K040169

3.0 **510(k) Summary**

APR 1 4 2004

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes Mandible External Fixator

Classification: Class II, 21 CFR §888.3030 – Single/multiple component bone fixation appliances and accessories.

Predicate Devices: Synthes Mini External Fixator

Device Description: Synthes Mandible External Fixator consists of the following components: An Adjustable Clamp – MR Safe; 4.0/2.5 Schanz Screws; 2.5 mm K-wires; 4.0 mm Pre-bent Titanium Rods; and 4.0 mm Carbon Fiber 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: The new device is considered to be substantially equivalent to the predicate device based on mechanical test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301-0800

Re: K040169
Trade/Device Name: Synthes Mandible External Fixator
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: January 23, 2004
Received: January 26, 2004

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.

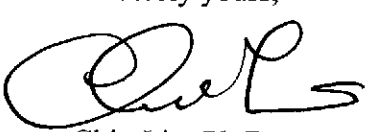
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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®

2.0 Indications for Use Statement

510(k) Number (if known): K040169

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 4/13/04 K040169