K040083

MAR 3 1 2004

3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Lisa M. Boyle (610) 647-9700
Name of the Device	Synthes External Midface Distractor
Device Classification	Class II, §872.4760 – External Mandibular Fixator and /or Distractor
Device Description	The Synthes External Midface Distractor is an external distraction osteogenesis device that attaches to the cranium and midface and is used to gradually lengthen the midface at the LeFort I, II, and III levels (including monobloc). The device consists of an external headframe, a central adjustment mechanism, a veridical central rod, horizontal crosspieces containing distraction screws, and separate footplates assemblies that attach to the zygoma and maxilla.
Indications	The Synthes External Midface Distractor is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy, the midface utilizing a LeFort II or III osteotomy, and / or the cranium utilizing a monobloc osteotomy in adult and pediatric populations where gradual bone distraction is required.
Substantial Equivalence	Documentation is provided which demonstrates that the Synthes External Midface Distractor is substantially equivalent to other legally marketed devices. The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K040083
Trade/Device Name: Synthes External Midface Distractor
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: January 14, 2004
Received: January 15, 2004

Dear Ms. Boyle:

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.

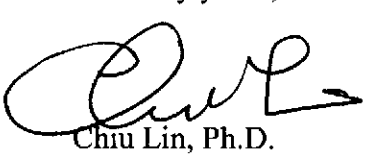
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K040083

Device Name: Synthes External Midface Distractor

Indications For Use: The Synthes External Midface Distractor is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy, the midface utilizing a Lefort II or III osteotomy, and/or the cranium utilizing a monoblloc osteotomy in adult and pediatric populations where gradual bone distraction is required.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 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)

Sara Ruoff

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

510(k) Number: K040083