JUN 29 1998

SYNTHES®

K981362

Attachment VII: **Summary of Safety and Effectiveness Information [510(k) Summary]**

SUBMITTER

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

Contact: Sheri L. Musgnung

COMMON OR USUAL NAME

Screw, Fixation, Intraosseous

DEVICE CLASSIFICATION:

Class II, 21 CFR 872.4880

PREDICATE DEVICE:

Howmedica's Mandibular Bone Distractor II (K960297)

DESCRIPTION:

The Synthes External MVMD is a bone lengthening and distraction device which is achieved by gradually activating the device in a linear, angular, and/or transverse fashion. Bone stabilization may also be achieved with this device after distraction.

The Synthes External MVMD is comprised of two interchangeable distraction arms, pin clamps, universal clamps, rods, flat head screws, and activation nuts. The pin clamps can accept 2.0 mm k-wires.

INTENDED USE:

Synthes External MVMD is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or post-traumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating any form of congenital mandibular hypoplasia, such as Hemifacial Micorsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

Synthes External MVMD is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1998

Ms. Sheri L. Musgnung
Regulatory Affairs Associate
SynthesÃ (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301

Re: K981362
Trade Name: SynthesÃ (USA) External Multi Vector Mandible Distractor
Regulatory Class: II
Product Code: DZL
Dated: April 14, 1998
Received: April 15, 1998

Dear Ms. Musgnung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K981362

Device Name: Synthes (USA) External Multi Vector Mandible Distractor

Indications For Use:

Synthes External MVMD is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or post-traumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating any form of congenital mandibular hypoplasia, such as Hemifacial Micorsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

Synthes External MVMD is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K981362