JUN 22 1998

K981075

SYNTHES®

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	Plate, Bone Screw, Fixation, Intraosseous
DEVICE CLASSIFICATION:	Class II, 21 CFR 872.4760 and 872.4880
PREDICATE DEVICE:	Howmedica's Hoffmann Mini Lengthening Fixator (K792561)
DESCRIPTION:	The Synthes Single Vector Distractor with Detachable Feet is a subcutaneous bone distractor activated by a drive component. It features two telescoping components activated by a jack screw, fixed to the bone with bone screws. Bone lengthening and distraction are achieved by gradually activating the device. Upon removal, the telescoping components and jack screw are disengaged and removed, leaving the subcutaneous foot plates in the patient.
INTENDED USE:	The Synthes Single Vector Distractor with Detachable Feet 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 forms of clefts of the lip and palate, and congenital mandibular hypoplasia, such as Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome. The Synthes Single Vector Distractor with Detachable Feet 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. The Synthes Single Vector Distractor with Detachable Feet can be for stabilization and advancement of the mid-face, in which a deficiency of mid-facial bone requires gradual bone distraction. Such deficiencies include, but are not limited to Plagiocephaly, Trigonocephaly, Scaphocephaly, and Brachycephaly.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 1998

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

Re: K981075
Trade Name: Synthes® (USA) Single Vector Distractor with Detachable Feet
Regulatory Class: II
Product Code: MQN
Dated: March 23, 1998
Received: March 24, 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®

Indications for Use Statement

510(k) Number (if known): K981075

Device Name: Synthes (USA) Single Vector Distractor with Detachable Feet

Indications For Use:

The Synthes Single Vector Distractor with Detachable Feet 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 forms of clefts of the lip and palate, and congenital mandibular hypoplasia, such as Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

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The Synthes Single Vector Distractor with Detachable Feet can be used for stabilization and advancement of the mid-face, in which a deficiency of mid-facial bone requires gradual bone distraction. Such deficiencies include, but are not limited to Plagiocephaly, Trigonocephaly, Scaphocephaly, and Brachycephaly.

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K98075