K974554

FEB 24 1998

Summary of Safety and Effectiveness Information [510(k) Summary]

1. **SPONSOR NAME AND ADDRESS**

Synthes (U.S.A.)
P.O. Box 1766
1690 Russell Road
Paoli, PA 19301
TEL: (610) 647-9700

Contact Person: Angela Silvestri, Regulatory Affairs Manager

2. **DEVICE NAME**

Common/Usual Name: Cranioplasty plate and plate fastener
Proprietary Name: Synthes (U.S.A.) Resorbable Fixation System

3 **CLASSIFICATION**

Cranioplasty plate and plate fastener have been classified as Class II devices, under 21 CFR 882.5320, 882.5330, and 882.5360.

4. **INTENDED USE**

Synthes Resorbable Fixation System is intended for fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midfacial fractures; and reconstructive procedures of the midface or craniofacial skeleton. Do not use in the mandible.

Synthes Resorbable Fixation System is not intended for: 1) areas with active infection; 2) patient conditions including: blood supply limitations, insufficient quantity of quality of bone, or latent infections. This device is not designed for use in the mandible or for use in full load bearing procedures.

5. **DEVICE DESCRIPTION**

Synthes (U.S.A.) Resorbable Fixation System contains various plates, meshes, and screws which are made from a resorbable copolymer, 70:30 poly(L/DL-lactide). The product line consists of a small system based upon 1.5 mm screws and a large system based on 2.0 mm screws.

The system is provided pre-sterilized by gamma radiation and is not intended to be resterilized by the user.

6. **SUBSTANTIAL EQUIVALENCE**

Synthes (U.S.A.) Resorbable Fixation System is substantially equivalent to Class II metallic implants, such as Synthes Maxillofacial Titanium Micro Set (K912932), and Synthes Midfacial System (K953806). Synthes (U.S.A.) Resorbable Fixation System is also substantially equivalent to other absorbable plates and screws, such as the Lorenz LactoSorb® Trauma Plating System (K955729, K960988), which is manufactured from 82:18 poly(L-lactide-co-glycolide)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Angela Silvestri
Manager, Regulatory Affairs
Synthes® (USA)
1303 Goshen Parkway
West Chester, Pennsylvania 19380

FEB 24 1998

Re: K974554
Trade Name: Synthes (U.S.A) Resorbable Fixation System
Regulatory Class: II
Product Code: JEY
Dated: December 3, 1997
Received: December 4, 1997

Dear Ms. Silvestri:

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

510(k) Number (if known): K974554

Device Name: Synthes (USA) Resorbable Fixation System

Indications for use:

Synthes Resorbable Fixation System is intended for fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midfacial fractures; and reconstructive procedures of the midface or craniofacial skeleton. Do not use in the mandible.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974554

Prescription Use Yes OR Over-The-Counter Use No
(Per 21 CFR 801.109)