DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2003

Ms. Angela Silvestri
Synthes USA
1690 Russell Road
Post Office Box1766
Paoli, Pennsylvania 19301

Re: K021928
Trade/Device Name: Synthes Resorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: December 11, 2002
Received: December 12, 2002

Dear Ms. Silvestri:

This letter corrects our substantially equivalent letter of September 6, 2002, regarding the Synthes Resorbable Fixation System. FDA had erred in originally clearing K021828 for market in 2002. At that time the second statement in your second Indications for Use Statement for this system should not have been cleared as a dental indication for use for the following reasons:

1. This second statement in your Indication for Use should have been submitted to the Orthopedics Branch of the Office of Device Evaluation for review. If you wish to make this claim, please submit a new premarket notification to the Orthopedics Branch of ODE for this indication for use.

2. The second statement in your Indication for Use Statement states that the device may be used for soft tissue prolapse in the iliac crest. This indication for use has not been previously cleared for devices used in the maxillofacial region.

3. Your second Indication for Use statement is contradictory to the contraindication mentioned in the second paragraph of that same Indications for Use Statement because the ilium is considered to be load bearing. This bone is an integral part of the pelvic girdle that supports loads from the thorax, arms, neck, and head.

We have reviewed your revised 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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613.

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

SYNTHES®

1. Indications for Use

510(k) Number (if known): K021928

Device Name: Synthes (USA) Resorbable Fixation System

Indications

Synthes Resorbable Fixation System devices (Plates, Meshes, Sheets, Screws and Tacks), are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton.

In addition, Resorbable Meshes, Sheets, Screws and Tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

Contraindications

These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Resorbable Fixation System devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

(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 Runyon

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

510(k) Number: K021928

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K021928

SEP 6 2002

3. 510(k) Summary

Submitter	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Bonnie Smith (610) 647-9700
Name of the Device	Synthes (USA) Resorbable Fixation System
Predicate Device	Synthes Resorbable Fixation System, Synthes Resorbable Tack System and Synthes Resorbable Meshes and Sheets.
Device Description	Synthes Resorbable Fixation System consists of resorbable plates, meshes, screws, tacks and accessory devices. Synthes Resorbable devices are manufactured from 70:30 poly (L/DL-lactide) and are available in various sizes. Resorbable meshes and sheets may be used as indicated, either alone or in conjunction with internal fixation devices (e.g., metallic plates and screws) that serve to further stabilize the treatment area. Resorbable Fixation System devices are provided pre-sterilized by gamma radiation. They are not intended to be resterilized by the user.
Indications for Use	Synthes Resorbable Fixation System devices (Plates, Meshes, Sheets, Screws and Tacks), are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets, Screws and Tacks may be used in non-load bearing applications for : ▪ Maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas ▪ Preventing soft tissue prolapse at bone graft donor sites, e.g., the iliac crest
Contraindications	These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Resorbable Fixation devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.