SYNTHES®

K022844

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

JAN 07 2003

SUBMITTER:	Synthes (USA) 1690 Russell Road Paoli, PA 19301
CONTACT:	Angela J. Silvestri (610) 647-9700 ext. 7190
DEVICE NAME:	Resorbable Contourable Mesh
CLASSIFICATION:	Class II, 21 CFR §872.4760: Bone Plate.
PREDICATE DEVICE:	Documentation was provided which demonstrated the Synthes Resorbable Contourable Mesh to be substantially equivalent to other legally marketed devices.
DEVICE DESCRIPTION:	Synthes Resorbable Contourable Mesh is a resorbable material sheet that comes in various sizes and shapes in perforated patterns that allow for better anatomical conformity. It is a part of the Synthes Resorbable Fixation System and can be used with the screws, tacks, and instruments in that system.
INTENDED USE:	Synthes Resorbable Fixation System devices (Plates, Meshes, 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.
MATERIAL:	Poly(L/DL-lactide)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2003

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Sythes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K022844
Trade/Device Name: Resorbable Contourable Mesh
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: December 11, 2002
Received: December 12, 2002

Dear Ms. Silvestri:

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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K022844

Device Name: Resorbable Contourable Mesh

Indications:

Synthes Resorbable Fixation System devices (Plates, Meshes, 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 Runner

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

510(k) Number: K022844