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3. **510(k) Summary**

Submitter:	Synthes (USA), 1230 Wilson Drive, West Chester, PA 19380
Company Contact:	Jeffrey L. Dow, JD (484) 356-9720 Dow.jeff@synthes.com
Name of Device:	Synthes OrthoMesh Resorbable Graft Containment System.
Device Classification / Common Name:	Class II, 21 CFR § 888.3030 – Bone Fixation Appliances and Accessories Product Classification Codes: HRS, Plate, Fixation, Bone; HWC, Screw, Fixation, Bone.
Predicate Device:	EBI LactoSorb® Graft Containment System (K033918), Synthes Resorbable Meshes and Sheets (K003788), W. Lorenz LactoSorb® Trauma Plating System ((Biomet) K960988, K971870, K992158, and K003281), and Synthes (USA) Rapid Resorbable Fixation System (K030069, K041611, K050204, K062789).
Intended Use:	The Synthes OrthoMesh Resorbable Graft Containment system is indicated for use in maintaining the relative position of weak bony tissue such as bone grafts, bone graft substitutes or bone fragments from comminuted fractures. OrthoMesh implants may be used alone (without traditional rigid fixation) to maintain the relative position of bone grafts, bone graft substitutes or bone fragments in non-load-bearing reconstructive procedures involving areas where bone stability has not been compromised, such as tumor resections and iliac crest graft harvest sites. OrthoMesh implants must be used in conjunction with traditional rigid fixation in load bearing applications to maintain the relative position of bone grafts, bone graft substitutes or bone fragments in reconstructive procedures involving long bones, flat bones, short bones, irregular bones, appendicular skeleton and thorax. These devices are not intended for use in the spine.
Contraindications:	Synthes OrthoMesh Graft Containment System is not intended for:

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1. Active infection.
2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.
3. Load bearing indications unless used in conjunction with traditional rigid fixation.
4. Use in the spine.

Device Description: The Synthes OrthoMesh Resorbable Graft Containment System is comprised of meshes of 0.5mm, 0.8mm and 1.2mm thickness, and lengths and widths ranging from 48mm to 125mm. The Synthes OrthoMesh Resorbable Graft Containment System is also comprised of screws with a diameter ranging from 1.5mm to 2.5mm, and a length ranging from 4mm to 8mm. These implants are made from the resorbable copolymer poly (L-lactide-co-glycolide) that resorbs *in vivo* by hydrolysis into lactic and glycolic acids, and that are then metabolized by the body. Synthes OrthoMesh implants are resorbed completely within approximately 12 months. The implants are provided sterile and are intended for single patient use. OrthoMesh may be held in place with screws.

Substantial Equivalence: Documentation is provided that demonstrates that OrthoMesh is substantially equivalent[1] to other legally marketed devices.

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[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug & Cosmetic Act, as amended, and as applied under 21 CFR Part 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalence under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein, shall be construed as an admission against interest under the U.S. patent laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes (USA)
% Mr. Jeffrey L. Dow
1230 Wilson Drive
West Chester, PA 19380

JUL 15 2008

Re: K073115
Trade/Device Name: Orthomesh
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 17, 2008
Received: June 23, 2008

Dear Mr. Dow:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number (if known): K073115

DEVICE NAME: Synthes OrthoMesh Resorbable Graft Containment System

INDICATIONS: The Synthes OrthoMesh Resorbable Graft Containment system is indicated for use in maintaining the relative position of weak bony tissue such as bone grafts, bone graft substitutes or bone fragments from comminuted fractures.

OrthoMesh implants may be used alone (without traditional rigid fixation) to maintain the relative position of bone grafts, bone graft substitutes or bone fragments in non-load-bearing reconstructive procedures involving areas where bone stability has not been compromised, such as tumor resections and iliac crest graft harvest sites.

OrthoMesh implants must be used in conjunction with traditional rigid fixation in load bearing applications to maintain the relative position of bone grafts, bone graft substitutes or bone fragments in reconstructive procedures involving long bones, flat bones, short bones, irregular bones, appendicular skeleton and thorax. These devices are not intended for use in the spine. The devices are not intended for load bearing indications unless used in conjunction with traditional rigid fixation

Prescription Use_____X____ OR Over-the-Counter Use_____
(Per 21 CFR 801. 109)

(PLEASE NO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073115