

K081623

SEP 08 2008

3.0 510(k) Summary

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Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Contact: Amnon Talmor
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Device Name: Synthes MatrixRIB Fixation System

Classification: Class II per 21 CFR §888.3030; Plate, Fixation, Bone
Class II per 21 CFR §888.3040; Screw, Fixation, Bone

Predicate Device: Acumed Rib Congruent Bone Plate System

Synthes Sternal Fixation System

MatrixMANDIBLE Plate and Screw System

OrthoPro Steinman Pins And Kirschner Wires

Device Description: The Synthes MatrixRIB Fixation System consists of bone plates, intramedullary (IM) splints and screws. All plates, IM splints and screws are manufactured from titanium alloy. The devices are provided sterile and non-sterile.

Intended Use: The Synthes MatrixRIB Fixation System is indicated for the fixation and stabilization of rib fractures, fusions and osteotomies of normal and osteoporotic bone.

Substantial Equivalence: Mechanical tests and engineering analyses were conducted to demonstrate the safety and effectiveness of the Synthes MatrixRIB Fixation System and support substantial equivalence to the predicates listed above.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes (USA)
% Mr. Amnon Talmor
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K081623
Trade/Device Name: Synthes MatrixRIB Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: HRS, HWC
Dated: June 6, 2008
Received: June 10, 2008

Dear Mr. Talmor:

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.

Page 2 - Mr. Amnon Talmor

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

2.0

Indications for Use

510(k) Number (if known): K081623

Device Name: Synthes MatrixRIB Fixation System

Indications for Use:

The Synthes MatrixRIB Fixation System is indicated for the fixation and stabilization of rib fractures, fusions and osteotomies of normal and osteoporotic bone.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO 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 K 081623