K102656

SYNTHES®

510(k) Summary

DEC 20 2010

Date Prepared	December 6, 2010
Submitter	SYNTHES (USA) 1301 Goshen Parkway West Chester, PA 19380 United States of America
Contact	Contact: Alan T. Haley haley.alan@synthes.com (484) 356-9763
Trade Name	Synthes Dentoalveolar Bone Fixation System
Common Name	Bone plates and screws
Classification Name	Bone plate, Class II, 21 CFR 872.4760 Intraosseous fixation screw or wire, Class II, 21 CFR 872.4880
Product Codes	Primary: JEY Subsequent: DZL
Predicate Devices	• Synthes 1.5mm/2.0mm Orthognathic Maxillary Plates and Screws (K980199) • Synthes 1.3 mm Self-Drilling Screw (K983485) • Osteo-Mesh TM-300 (K984230) • Synthes Craniofacial Plates (K021642) • Synthes Poly (L-Lactide-Co-Glycolide) Resorbable Fixation System (K030069) • 1.3 & 1.5mm Contourable Titanium (Ti.) Mesh Plates (K033121)
Device Description	The Synthes Dentoalveolar Bone Fixation System is a plate, mesh, and screw system intended to be implanted intraorally for use 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 maxillary and/or mandibular areas, including the dentoalveolar ridge. *Screws* The System includes 1.3 mm, 1.5 mm, and 2.0 mm diameter cortex screws in lengths from 3 mm to 20 mm. Screws are offered with both self-tapping and self-drilling tips. Screws are manufactured from titanium alloy (Ti-6Al-7Nb). *Plates and Meshes* The System includes plates and meshes that come in a variety of configurations to accommodate various dentoalveolar defect sites. The plates attach to bone via titanium cortex screws. Plates and meshes are manufactured from commercially pure titanium.

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Intended Use

The Synthes Dentoalveolar Bone Fixation System is intended for use 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 maxillary and/or mandibular areas, including the dentoalveolar ridge.

Technological Characteristics

The Synthes Dentoalveolar Bone Fixation System devices are similar to the predicate devices in terms of indications, mechanical properties, dimensions, principles of operation, and design (i.e. screws, plates, and mesh).

The titanium used in the Synthes Dentoalveolar Bone Fixation System is used in all of the predicate devices with the exception of the Poly (L-Lactide-Co-Glycolide) Resorbable Fixation System. The non-clinical testing data discussed below show that the subject devices have equivalent or better mechanical performance when compared to the predicate devices and that the difference in material does not raise new issues of safety and effectiveness.

Clinical Testing Data

No clinical testing was performed to support this submission.

Non-Clinical Testing Data

Mechanical testing was performed to compare the titanium alloy screws to screws from the predicate Poly (L-Lactide-Co-Glycolide) Resorbable Fixation System. Testing was performed to measure resistance to axial pullout, shear strength, and safety factor during insertion (the ratio of failure torque to insertion torque).

Mechanical testing was used to compare the titanium plates to plates from the predicate Poly (L-Lactide-Co-Glycolide) Resorbable Fixation System. Testing was performed to measure load at 0.2% offset yield and bending strength.

Mechanical testing was used to compare the titanium mesh to the predicate Osteo-Mesh TM-300. Testing was performed to measure peak load, displacement at peak, load at 0.2% offset yield, bending stiffness, and bending strength.

The results of the non-clinical testing described above support substantial equivalence by demonstrating that the mechanical performance of the Synthes Dentoalveolar Bone Fixation System devices is equivalent to or better than the predicate devices.

Substantial Equivalence to Predicate Devices

In conclusion, the Synthes Dentoalveolar Bone Fixation System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Non-clinical testing data demonstrate that differences in the technological characteristics do not raise new issues of safety or effectiveness. The information presented supports substantial equivalence of the Synthes Dentoalveolar Bone Fixation System to the predicate devices.

(end of summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Alan T. Haley
CMF Regulatory affairs specialist
SYNTHES (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

DEC 2 0 2010

Re: K102656
Trade/Device Name: Synthes Dentoalveolar Bone Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: December 6, 2010
Received: December 7, 2010

Dear Mr. Haley:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102656

SYNTHES®

2.0 Indications for Use

DEC 2 0 2010

510(k) Number (if known): _____

Device Name: Synthes Dentoalveolar Bone Fixation System

INDICATIONS FOR USE: The Synthes Dentoalveolar Bone Fixation System is intended for use 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 maxillary and/or mandibular areas, including the dentoalveolar ridge.

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)

Susan Runner

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

510(k) Number: K102656