K093299

SYNTHES®

DEC 16 2010

510(k) Summary

Device Name: Synthes Orthodontic Bone Anchor System

Date Prepared: July 30, 2010

Sponsor:
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

Classification: Class II, §872.3640, Endosseous dental implant

Predicate Devices: Synthes Orthodontic Bone Anchor System (K063473)
Jeil Medical Corporation Dual Top Anchor System Screws (K033767)

Device Description: The Synthes (USA) Orthodontic Bone Anchor System is intended to be implanted intraorally and used as an anchor for orthodontic procedures. The System includes screw anchors, plate anchors, instruments, and a module case for storage and sterilization.

Screw Anchors
The screw anchor portion of the system consists of 1.55 mm self-drilling and self-tapping screw anchors which incorporate a non-threaded gingival collar beneath the screw head to protect the soft tissue. Once implanted, orthodontic appliances such as archwires, elastics, and springs can be attached to the head of the anchor.

The screw anchors are manufactured from titanium alloy (Ti-6Al-7Nb).

Plate Anchors
The plate anchor portion of the system consists of T-shaped plate anchors which are attached to the bone via 1.55 mm cortex screws and 1.85 mm emergency screws. The plate anchors are offered in three designs (mesh, bracket, and domed) to allow attachment of orthodontic devices such as brackets, archwires, elastics, and springs.

The plate anchors are manufactured from commercially pure titanium. The screws used to fix the plate anchors to the bone are manufactured from titanium alloy (Ti-6Al-7Nb)

(continued on next page)

K093299

SYNTHES®

Intended Use:	The Orthodontic Bone Anchor (OBA) System screw anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adolescents greater than age 12 and adults. The Orthodontic Bone Anchor (OBA) System plate anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adults.
Non-Clinical Testing Data:	The Synthes Orthodontic Bone Anchor System was tested for resistance to pullout under clinical loads by means of axial, shear, and cantilever loading. Screws were also tested for insertion torque, removal torque, and yield and failure torque.
Substantial Equivalence to Predicate Devices:	The proposed devices are similar to the predicate devices identified above in terms of indications, principles of operation (provide fixed anchorage for orthodontic movement of teeth), device design/geometry, and materials. Information presented supports substantial equivalence.

(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

DEC 16 2010

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

Re: K093299
Trade/Device Name: Synthes Orthodontic Bone Anchor System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: December 10, 2010
Received: December 13, 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,

for

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

SYNTHES®

Indications for Use

510(k) Number (if known): K093299

Device Name: Synthes Orthodontic Bone Anchor System

INDICATIONS FOR USE: The Orthodontic Bone Anchor (OBA) System screw anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adolescents greater than age 12 and adults.

The Orthodontic Bone Anchor (OBA) System plate anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adults.

Prescription Use ____X____ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093299