SYNTHES® K063473

3.0 **510(k) Summary** Page 1 of 1

Sponsor:
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-5000

Contact:
Deborah L Jackson, RAC
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6948

MAR 0 8 2007

Device Name: Synthes Orthodontic Bone Anchor System

Classification:
Class II, §872.3640 – Endosseous Implant Screw
Class II, §872.4760 - Bone plate
Class II, §872.4880 - Intraosseous fixation screw or wire

Predicate Device:
KLS-Martin Ortho Anchorage System – Screw Anchors K033483
KLS Martin Ortho Anchorage System – Plate Anchors K040891

Device Description: The Synthes (USA) Orthodontic Bone Anchor System is a plate and screw system designed to be implanted intraorally and used as an anchor for orthodontic procedures. 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 various designs for attachment to the orthodontic device. 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 which protects the soft tissue.

Intended Use: The Orthodontic Bone Anchor (OBA) System is intended to be implanted intraorally and used as an anchor for orthodontic procedures.

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Deborah L. Jackson
Regulatory Affair Specialist
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAR 0 8 2007

Re: K063473
Trade/Device Name: Synthes (USA) Orthodontic Bone Anchor System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 26, 2007
Received: February 27, 2007

Dear Ms. Jackson:

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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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**

510(k) Number (if known): K063473

Device Name: Synthes (USA) Orthodontic Bone Anchor System

Indications for Use: The Orthodontic Bone Anchor (OBA) System is intended to be implanted intraorally and used as an anchor for orthodontic procedures.

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 Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K063473