SYNTHES®

APR 12 2005

K043555

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes Alveolar Ridge Distractor

Classification: Class II, §872.4760 – Bone Plate

Predicate Device: KLS Martin – Track 1.0 & 1.5mm System
Lorenz Surgical, Inc – Lorenz Distraction System

Device Description: The Synthes Alveolar Ridge Distractor is an extraosseous distraction device consisting of a distractor body, a transport plate, a base plate, and a vector control mechanism. It is intended to be placed submucosally, with the base plate fastened to the stationary segment of the mandible or maxilla and the transport plate fastened to the mobile bone segment. The plates are fixed to the bone using 1.5 mm cortex screws.

Intended Use: The Synthes Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of trauma, resorption after dental extraction, periodontal disease, tumor resection, and congential deformity.

Substantial Equivalence: Documentation was provided which demonstrated the Synthes Alveolar Ridge Distractor to be substantially equivalent to other legally marketed devices.

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 and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency 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 US 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

APR 12 2005

Ms. Kathy Anderson
Regulatory Affairs Manager
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K043555
Trade/Device Name: Synthes (USA) Alveolar Ridge Distractor
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: March 17, 2005
Received: March 18, 2005

Dear Ms. Anderson :

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): K043555

Device Name: Synthes (USA) Alveolar Ridge Distractor

Indications for Use:

The Synthes Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of:

- Trauma
- Resorption after dental extraction
- Periodontal disease
- Tumor resection
- Congenital deformity

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 K043555