SYBRON DENTAL SPECIALTIES

K061230

AUG - 3 2006

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
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Colleen Boswell - Contact Person

Date Summary Prepared: May 2006

Device Name:

- Trade Name – *Vectors Temporary Anchorage System*
- Common Name – Orthodontic Implant Screw
- Classification Name – Implant, Endosseous Dental, per 21 CFR § 872.3640

Devices for Which Substantial Equivalence is Claimed:

- Medicon eG, *Aarhus Anchorage System*
- Dentaurum, *Tomas Pin*
- Imtec Corporation, *Ortho Implant*
- Mondeal Medical Systems, *Lomas Quattro*

Device Description:

The *Vectors Temporary Anchorage System* consists of sterile, single-use titanium screws that are available in 6, 8, 10, and 12mm lengths which are designed to aid in dental movement by providing a rigid skeletal fixation point. They are inserted into the bone and serve as a temporary anchor for various orthodontic tooth movements. The self-drilling thread design allows for easy insertion and removal with the use of the system's driver. The product is sterilized using gamma radiation.

Intended Use of the Device:

The *Vectors Temporary Anchorage System* is intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily and is removed after orthodontic treatment. The screw is sterile and is intended for single use only.

Substantial Equivalence:

The *Vectors Temporary Anchorage System* is substantially equivalent to other legally marketed devices in the United States. The *Vectors Temporary Anchorage System* is composed of the same material and is substantially equivalent in application and function to the *Aarhus Anchorage System Screws, Tomas Pin, Ortho Implant* and *Lomas Quattro* marketed by Medicon eG, Dentaurum, Imtec Corporation and Mondeal Medical Systems, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2007

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
100 Bayview Circle, Suite 6000
Newport Beach, California 92660-8915

Re: K061230
Trade/Device Name: Vectors Temporary Anchorage System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: OAT
Dated: July 26, 2006
Received: July 27, 2006

Dear Ms. Boswell:

This letter corrects our substantially equivalent letter of August 3, 2006.

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 (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 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 continue 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Vectors Temporary Anchorage System

Indications for Use:

The *Vectors Temporary Anchorage System* is a threaded titanium dental implant screw intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily and is removed after orthodontic treatment. The screw is sterile and is intended for single use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number: K061230