K081393

AUG 21 2008

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)1)

Submitter Information

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Contact Person: Carri Graham

Date: May 16, 2008

807.92(a)2)

Trade Name: Orthodontic Temporary Anchorage Implant Screw

Common Name: Temporary Anchoring Device

Classification Name(s): Implant, Endosseous, Orthodontic

Classification Number: OAT – 21CFR 872.3640

807.92(a)3)

Predicate Device(s)

Ortho Organizers	Ancor Pro Temporary Orthodontic Anchorage System	K061266
Dentaurum	Tomas Temporary Micro Anchorage	K042965
T.O.A.D.S.	Temporary Anatomical Anchor Device	K063149

Device Description

The Orthodontic Temporary Anchorage Implant Screws are available in three sizes, 6mm, 8mm and 10mm. The head of the screw allows insertion by either a screwdriver type instrument mated with a slot head or a socket driver type instrument matched with the dual socket design. The neck is long enough, with a .022 hole, to engage auxiliaries and short enough to maintain a low profile. The screws are intended for immediate loading and are highly polished to prevent osseointegration. The screws are made from the same materials, 100% biocompatible titanium ASTM F136, as most of the predicate devices and are sold as non-sterile with instructions to use steam sterilization methods or other accepted techniques used by the orthodontist.

807.92(a)5)

Intended Use(s)

The Orthodontic Temporary Anchorage Implant Screws are intended to provide a fixed anchorage point for the attachment of intraoral orthodontic appliances to facilitate the orthodontic movement of teeth. They are intended for temporary use and should be removed after orthodontic treatment has been completed. The screws are intended for single use only.

807.92(a)6)

Technological Characteristics

The Orthodontic Temporary Anchorage Implant Screws have the same intended use and indications, are made from the same or similar materials, and are very similar in design as the predicate devices: Ancor Pro Temporary Orthodontic Anchorage System (Ortho Organizers), Tomas Temporary Orthodontic Micro Anchorage (Dentaurum, Inc.) and the Temporary Anatomical Anchor Device System, TADDS, (T.O.A.D.S, LLC).
The Orthodontic Temporary Anchorage Implant Screw is equivalent to the predicate devices both by material and overall design and function. All screws have self tapping threads and multiple sizes to accommodate the orthodontist needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

G & H Wire Company
C/o Ms. Carri Graham
Consultant
The Anson Group, LLC
11460 North Meridian Street, Suite 150
Carmel, Indiana 46032

AUG 21 2008

Re: K081393
Trade/Device Name: Orthodontic Temporary Anchorage Implant Screw
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: August 15, 2008
Received: August 18, 2008

Dear Ms. Graham:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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: Orthodontic Temporary Anchorage Implant Screw

Indications for Use: Temporary anchorage screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. The screw is used temporarily and is removed after orthodontic treatment has been completed.

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)

Susan Runner

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

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