510(k) Summary

K061266

JUL 3 1 2006

Ortho Organizers, Inc.
Temporary Orthodontic Anchor

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Ortho Organizers, Inc. 1619 S. Rancho Santa Fe Road San Marcos, CA 92078 Telephone (760) 471- 0206 FAX (760) 752-7650
Official Contact:	Robert Riley Vice President of Operations
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Implant, Endosseous, Root-Form
Trade/Proprietary Name:	Ortho Organizers Temporary Orthodontic Anchor
Common Name:	Orthodontic Anchor

DEVICE CLASSIFICATION

Implant, Endosseous, Root-Form is classified as Class II (21 CFR 872.3640). The product code is DZE. This device classification is reviewed by the Dental Devices Branch.

INTENDED USE

The Ortho Organizers Temporary Orthodontic Anchor is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

DEVICE DESCRIPTION

The Ortho Organizers Temporary Orthodontic Anchor is a device that is temporarily implanted in the alveolar ridge to provide a fixed anchorage point for various orthodontic tooth movements.

Design

It is a single-piece design that features a threaded shaft and a low profile proximal head. The supragingival head has an upper button and undercut that serves as an attachment point. The tapered conical section below the button incorporates a transverse circular opening which also serves as an attachment point. Vertical flats below the conical section enable use of tools to turn the device into its fully implanted position. The head terminates in a collar that separates the attachment points from the threaded portion of the device. The device is available with either a short collar or a long collar to accommodate variations in soft tissue thickness.

Material

The Ortho Organizers Temporary Orthodontic Anchor is made of titanium alloy conforming to the requirements of ASTM F 136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*

Sterilization

The Ortho Organizers Temporary Orthodontic Anchor will be sold non-sterile and is intended to be sterilized prior to use.

EQUIVALENCE TO MARKETED DEVICE

Ortho Organizers, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Ortho Organizers Temporary Orthodontic Anchor is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

The intended use, design, materials and functional characteristics of the Ortho Organizers Temporary Orthodontic Anchor and the predicate devices are substantially the same. All are indicated for temporary fixed anchorage of orthodontic appliances and accessories used in the movement of teeth. The basic design of each consists of a threaded shaft for bone anchorage and a contoured head for attachment of various orthodontic appliances and accessories. Each is made of Ti-6Al-4V titanium alloy, a well-proven material for implantable devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2007

Ortho Organizers, Incorporated
C/O Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K061266
Trade/Device Name: Ortho Organizers Temporary Orthodontic Anchor
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 Mr. Larson:

This letter corrects our substantially equivalent letter of July 31, 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): K061266

Device Name:

Ortho Organizers Temporary Orthodontic Anchor

Indications for Use:

The Ortho Organizers Temporary Orthodontic Anchor is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Robert Beck DDS for Dr Susan Runner

Concurrence of CDRH, Office of Device Evaluation (ODE)

...n Sign-Off)
...n of Anesthesiology, General Hospital
...ion Control, Dental Devices
...ber K061266