K120861

FEB 2 1 2013

Creekside Orthodontics
136 E. Mallard Dr.
Boise, Idaho 83706
Contact Name: Dr. John T. Kalange
208-342-0212
208-342-0323 (Fax)
Summary Preparation Date: 1/24/2013
510(K) Summary of Safety and Effectiveness

1. Identification of the Device:

Proprietary-Trade Name: Fin-S Orthodontic/Dental Microimplant
Classification Name: Implant, Endosseous, Product Code OAT
Common/Usual Name: Dental Implant

2. Equivalent Legally Marketed Devices:

Dentaurumn Tomas-pin (K042965),
Jeil Medical Dual Top Anchor SystemScrews (K033767),
IMTEC MIDI Ortho (K042289)
Dentos AbsoAnchor(K060126)

3. Description of the Device:

The Fin-S Orthodontic/Dental Microimplant is composed of Titanium-6 Aluminum-4 Vanadium Alloy Grade 5 (ATSM F1472-08, ISO 5832-2:1999) material. It has been designed specifically for orthodontic or dental use and has a head which includes two round holes for insertion of various ligatures, coil springs, and elastomers. It also includes two rectangular slots which accept various forms of orthodontic archwires. The smaller diameter of implant, allows its insertion into many areas of the upper and lower jaws and between the roots of teeth. It is divided into four groups of various lengths: Round Head (6,8,10,12mm), Palatal (4,6,8,10mm), Reverse Thread (6,8,10,12mm), and Long Head (6,8,10,12mm). The round head design is the primary device which includes all of the design elements. The Palatal design is essentially the same as the Round Head Design, but has a shortened soft tissue collar. The Reverse Thread design is the same as the basic Round Head Design but has threads that are reversed and allow for counter-clockwise insertion. Finally, The Long Head design is the same as the basic Round Head Design, but has a lengthened soft tissue collar.

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4. Indications for Use:

The Fin-S Orthodontic/Dental Microimplant is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. This device is intended for single use only.

5. Potential Adverse Affects and Complications (common to all devices of this type):

* Metal sensitivity or allergic reaction
* Pain or discomfort due to presence of device
* Infection

6. Non-clinical Testing Data Regarding Cytotoxicity:

Cytotoxicity testing of the Fin-S Orthodontic/Dental Microimplant was performed utilizing a direct-contact test according to ISO 10993-5:1999 and ISO 10993-12:2004. Specifically, an established cell line was obtained from a recognized cell repository. These cells were cultured according to accepted methods, and the cultures were exposed to direct contact with the microimplant which is composed of Ti6Al4V titanium based alloy. Cytotoxicity was evaluated by microscopically examining the cell cultures for visual clues of cytotoxicity when compared to a control culture. The Fin-S Orthodontic/Dental Microimplant demonstrated to be non-cytotoxic and is therefore biocompatible.

7. Sterilization Validation Testing:

Sterilization testing of the devices was performed using Bacillus atrophaeus and Geobacillus Stearothermophilus spore strips and inoculated microimplants using the same organisms. The moist heat sterilization instructions provided in the directions for use have been validated to a Sterility Assurance Level of 10^{-6} according to ISO 17665-1 and ISO 17665-2 with the overkill method. Additionally, the dry heat instructions provided in the directions for use have been validated to a Sterility Assurance Level of 10^{-6} according to ISO 20857 with the overkill method.

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8. Safety and Effectiveness, Comparisons to Predicate Devices:

Product Comparison:

Device Name	Fin-S Orthodontic/ Dental Microimplant	Absoanchor	Tomas-pin	Dual Top Anchor System	MDI Ortho
Product Code	OAT	DZE	DZE	DZE	DZE
Applicant	Dr. John T. Kalange	Dentos, Inc.	Dentarum	Jeil Medical Group	IMTEC Corp.
510(K) #	K120861	K060126	K042965	K033767	K042289
Intended Use	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth
Sterility	Non-sterile: steam sterilize before use	Non-sterile: steam sterilize before use	Sterile	Non-sterile: steam sterilize before use	Sterile
Diameter	1.4mm	1.2mm-1.8mm	1.2mm	1.4-2.0mm	1.8mm
Length	Round Head 6mm-12mm Palatal Head 4mm-10mm Reverse Thread 6mm-12mm Long Head 6mm-12mm	4.0mm-12mm	8.0mm-10mm	6.0mm-12mm	6.0mm-10mm

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9. Conclusion Statement:

The information provided in this submission demonstrates the substantial equivalence of the Fin-S Orthodontic/Dental Microimplant to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

John T. Kalange, DDS, MS
Owner
Creekside Orthodontics
136 East Mallard Drive
BOISE ID 83706

Re: K120861
Trade/Device Name: Fin-S Orthodontic/Dental Microimplant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: January 24, 2013
Received: February 12, 2013

Dear Dr. Kalange:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, DDS, MA

Mary S. Runner
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K120861

Device Name: Fin-S Orthodontic/Dental Microimplant

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Runner
2013.02.14
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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120861