K060126

MAY 16 2006

Dentos, Incorporated
Dong Bu B/D 2F #22, 251,4Ga, Dong-In-Dong Jung-Gu
Daugu, South Korea, 700-424
Phone: 82-53-592-5908 Fax: 82-53-592-5909
Contact: Myung Sub Kim, Assistant Manager of Quality Management
Summary Preparation Date: 10/25/05

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: AbsoAnchor (Orthodontic Microimplant)
   Classification Name: Implant, Endosseous, Product Code DZE
   Common/Usual Name: Dental Implant

2. Equivalent Legally Marketed Devices:
   Dentaurum Tomas-pin (K042965), Jeil Medical Dual Top Anchor System Screws (K033767), and IMTEC MDI Ortho (K042289).

3. Description of the Device:
   The Dentos AbsoAnchor Orthodontic Microimplant is composed of Titanium-6Aluminum-4Vanadium ELI Alloy Grade 5 (ASTM F136) material. It has been designed specifically for orthodontic use and has a button-like head and a bracket-like head with a small hole that accepts ligatures, coil springs, and elastomers. Gingival impingement by these attachments is reduced due to the slanted neck of the implant head. The smaller diameter of AbsoAnchor (1.2mm – 1.8mm) allows its insertion into many areas of the maxilla and mandible and between roots of adjacent teeth. It is classified into 2 implant groups: Taper and Cylinder. It also consists of 8 different head styles: small head, no head, long head, circle head, fixation head, bracket head, bracket head-left handed screw, OMAS mushroom.

4. Indications for Use:
   To provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth

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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. Safety and Effectiveness, Comparisons to Predicate Devices:

Device Name	AbsoAnchor	Tomas-pin	Dual Top Anchor System	MDI Ortho
Product Code	DZE	DZE	DZE	DZE
Applicant	Dentos, Inc	Dentaurum, Inc	Jeil Medical Corp.	IMTEC Corp.
510(k) #	This submission	K042965	K033767	K042289
Material	Titanium6Aluminum-4Vanadium ELI Alloy Grade 5 (ASTM F136-98)	Titanium Grade 5	Titanium Alloy (ASTM F136-98)	Titanium Alloy
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
Sterility	Non-sterile: steam sterilize before use	Sterile	Non-sterile steam sterilize before use	Sterile
Diameter	1.2mm-1.8mm	1.2mm	1.4mm-2.0mm	1.8mm
Length	4.0mm-10mm &12mm	8.0-10mm	6.0mm-12mm	6.0mm,8.0mm & 10mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2006

Dentos, Incorporated
C/O Ms. Anna Shafto, BS, MT
Health Science Research Assistant
University of Michigan School of Dentistry
1011 North University Avenue
Ann Arbor, Michigan 48109

Re: K060126
Trade/Device Name: AbsoAnchor Microimplant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 28, 2006
Received: May 1, 2006

Dear Ms. Shafto:

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.

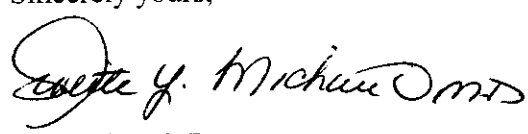
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

K060126

Indications for Use Statement

510(k) Number (if known): K060126

Device Name: AbsoAnchor Microimplant

Indications for Use:

The intended purpose of the AbsoAnchor microimplant is 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runne

Division Sign-Off

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K060126