K071490

510(k) SUMMARY

Submitter's name: Leone SpA
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Name of contact person: Elia Ladani
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Date the summary was prepared: August 3, 2007

Name of the device: Leone orthodontic mini implant
Trade or proprietary name: Leone orthodontic mini implant
Common or usual name: Orthodontic implant
Classification name: Endosseous Dental Implant

The legally marketed device to which we are claiming equivalence [21 CFR 807.92(a)(3)]:

Dentos Inc, Dentos AbsoAnchor orthodontic microimplant (K060126)

Description of the device:

The Leone orthodontic mini implant is a medical device made of stainless steel for surgical use (ISO 5832-1). The orthodontic mini implant is a one-piece endosseous mini implant where the endosseous portion is a right-hand thread screw, while the head section is made of a smooth tapered neck. It is available in different diameters, lengths and head shapes.

Intended use:

The Leone orthodontic mini implant is an implant device providing a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily in the

maxillary and mandibular bone and must be removed after orthodontic treatment has been completed.

Summary of the technological characteristics of our device compared to the predicate device:

Device Name	Leone orthodontic mini implant	Dentos AbsoAnchor orthodontic microimplant
Product code	DZE	DZE
Regulation no.	872.3640	872.3640
Applicant	Leone SpA (Italy)	Dentos, Inc (Korea)
510(k)	This submission	K060126
Intended use	Provide a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily in the maxillary and mandibular bone and must be removed after orthodontic treatment has been completed.	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth
Material	Surgical stainless steel ISO 5832-1	Surgical titanium alloy ISO 5832-3
Biocompatibility	Biocompatible.	Biocompatible.
Sterility	Non-sterile. It is recommended to sterilize with steam autoclave before use.	Non-sterile. Steam sterilize before use.

Conclusion:
According to the similarities specified in the above comparison table between the current device Leone orthodontic mini implant and the predicate device, in indications for use, technology and performance specifications as supported by the results of the testing performed we conclude that the Leone orthodontic mini implant is substantially equivalent to the Dentos AbsoAnchor orthodontic microimplant, device currently marketed in USA under the Federal Food, Drug and Cosmetic Act.
The Leone orthodontic mini implant raises no new issues of safety or effectiveness. Therefore, safety and effectiveness are reasonably assured, and substantial equivalence is supported, justifying 510(k) clearance of the Leone orthodontic mini implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2008

Mr. Elia Ladani
Quality Manager
Leone SpA
50 Via P. a Quaracchi
Sesto Fiorentino I-50019
ITALY

Re: K071490
Trade/Device Name: Leone Orthodontic Mini Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 11, 2008
Received: February 14, 2008

Dear Mr. Ladani:

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.

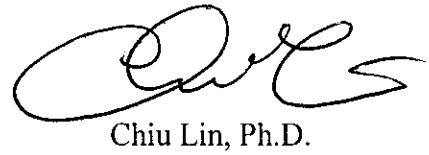
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071490

Device Name: Leone orthodontic mini implant

Indications For Use:

The Leone orthodontic mini implant is an implant device providing a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily in the maxillary and mandibular bone and must be removed after orthodontic treatment has been completed.

Prescription Use √ (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 Runner

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

510(k) Number: K071490

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