JAN - 8 2014

Dental Morelli Ltda.

SECTION 7

510(k) SUMMARY

Proprietary Name	Orthodontic Miniscrew for Absolute Anchorage
Date Prepared	December 1, 2013
Submitter	DENTAL MORELLI LTDA Alameda Jundiaí, 230 – Jardim Saira - Sorocaba CEP: 18085-090 Brazil Telephone: 55 (15) 3238-8200
Official Contact	Lilian Llull / Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL– (305) 377-0077

Common Name	Orthodontic Mini Implants
Classification Name	Endosseous Orthopedic Implants
Regulation Number & Product Codes	OAT - 21 CFR 872.3640
Proposed Regulatory Class	Class II
Predicate Device Identification	Aarhus Anchorage System K041527

Description of Proposed Device

The Orthodontic Miniscrew for Absolute Anchorage is an implantable medical device used as a temporary skeletal anchorage point for orthodontic movements. The mini screw is intended to receive low intensity static clinical loads. Maximum dynamic forces may occur at low frequencies for short periods; which is inadequate to compromise the performance of the product through fatigue. The device is available in different lengths (6, 8, 10, mm), diameter 1.5 mm, and supplied in sealed sterile polyethylene bags.

Intended Use

The Orthodontic Miniscrew for Absolute Anchorage is threaded titanium dental implant screws intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily and is removed after orthodontic treatment.

Device Comparison

	Orthodontic Miniscrew for Absolute Anchorage by Dental Morelli K130476	Aarhus Anchorage System K041527
Indications of Use	Threaded titanium dental implant screw intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily	Threaded titanium dental implant screw intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction
Anatomical Sites	Jaw	Jaw
Location of Use, hospital, home, ambulance, etc	Use only by professional dentists / orthodontists	Use only by professional dentists / orthodontists
Diameter and Length	Diameter ranges from 1.5 mm, length ranges from 6-10 mm	Diameter ranges from 1.5-2 mm, length ranges from 9-11 mm
Performance	Self-trapping/Self-drilling	Self-trapping/Self-drilling
Materials	Titanium Alloy ASTM F 136	Titanium Alloy ASTM F 136
Biocompatibility	Titanium Alloy in medical grade according to ASTM-F 136 is accepted for endosseous implant	Titanium Alloy in medical grade according to ASTM-F 136 is accepted for endosseous implant
Compatibility with the environment and other devices	Titanium Alloy in medical grade according to ASTM-F 136 is accepted for endosseous implant	Titanium Alloy in medical grade according to ASTM-F 136 is accepted for endosseous implant
Sterility	Gamma Radiation	Gamma Radiation
Mechanical Safety	Tensile strength of material according to ASTM – F 136 is accepted for endosseous implants	Tensile strength of material according to ASTM – F 136 is accepted for endosseous implants

Substantial Equivalence

The Orthodontic Miniscrew for Absolute Anchorage is made from the same material as the predicate Aarhus Anchorage System K041527 and has similar dimensions and characteristics. Micro Titanium Plate System following ASTMF 136-98 which is generally used in this kind of bone screw therefore no further testing was conducted.

All reports show that the Orthodontic Miniscrew for Absolute Anchorage is substantially equivalent in design, material, intended use and function to Aarhus Anchorage System K041527. They are made of the same material and have similar dimensions and characteristics. Potential adverse effects are identical. Both devices are manufactured from titanium ASTMF 136-98 which is generally used in this kind of bone screw.

Performance Testing

The Orthodontic Miniscrew for Absolute Anchorage conforms to the following standards:

- ASTM F136
- ASTM F1980-07
- ISO 11137

ASTM F136: This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy (R56401) to be used in the manufacture of surgical implants. The products are classified into: strip, sheet, plate, bar, forging bar, and wire. The heat analysis shall conform to the chemical composition requirements specified. Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Tension test and bend test shall be performed to meet the requirements specified.

ASTM F1980-07: The loss of sterile barrier system integrity may occur as a result of physical properties of the materials and adhesive or cohesive bonds degrading over time and by subsequent dynamic events during shipping and handling.

ISO 11137: Sterilization of Health Care Products Package provides the requirements for developing, validating and routinely controlling the sterilization process of medical devices. In addition to providing the requirements for the sterilization process of medical devices, this package also considers the

products' environment, personnel and their hygiene, packaging / storage, sterilization doses and more to inactivate microbiological contaminants on medical devices.

Conclusion

Testing was done to determine the torque levels, forces and insertion lengths while inserting the Orthodontic Miniscrew for Absolute Anchorage. The level of torque is comparable to the Aarhus Anchorage System K041527. Which were investigated with the measurement equipment under the same parameter. In conclusion it can be said that in all respects based on Intended Use, Indications of Use, Construction Material, Performance and Bench Tests that the Orthodontic Miniscrew for Absolute Anchorage and the Aarhus Anchorage System K041527 are substantially equivalent.

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

January 8, 2014

DENTAL MORELLI LTDA
C/O Ms. Lillian Llull
Senior Partner
TechLink International Consulting
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

Re: K130476
Trade/Device Name: Orthodontic Miniscrew for Absolute Anchorage
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: December 1, 2013
Received: December 6, 2013

Dear Ms. Llull:

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 contact 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. 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,

Kwame O. Ulmer-S for

Erin I. Keith, M.S.
Acting 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 Statement

510(k) Number: K130476

Device Name: Orthodontic Miniscrew for Absolute Anchorage

Indications for Use:

Dental Morelli Orthodontic Dental Implant is a threaded titanium dental implant screw intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily and is removed after orthodontic treatment.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

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