K131197

Dental Morelli Ltda.

SECTION 6

510(k) SUMMARY

Proprietary Name	Edgewise Ceramic Brackets; Roth Ceramic Brackets
Date Prepared	April 15, 2013
Submitter	DENTAL MORELLI LTDA Alameda Jundiaí, 230 – Jardim Saira - Sorocaba CEP: 18085-090 Brazil Telephone: 55 (15) 3238-8200
Official Contact	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL– (305) 377-0077
Common Name	Orthodontic Ceramic Brackets
Trade Name	Edgewise Ceramic Brackets; Roth Ceramic Brackets
Classification	Class II
Product Code	NJM
Classification Panel	Dental
Regulation Numbers	21 CFR 872.5470
Substantial Equivalence	K102803 Clarity Advanced Ceramic Brackets

AUG 27 2013

Description of Proposed Device

Edgewise and Roth Ceramic Brackets are intended to be bonded to teeth, upon which an orthodontic wire is used to move the teeth to new positions. The Morelli bracket consists of a translucent alumina body. The bracket is uncoated. The Morelli bracket is not self-bonding and requires a primer and adhesive to bond the bracket to the teeth.

Indications for Use

Edgewise and Roth Ceramic Brackets are intended for use in orthodontic treatments. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Device Comparison Table

	Edgewise Ceramic Brackets by Dental Morelli	Roth Ceramic Brackets by Dental Morelli	Clarity Advance Ceramic Brackets by 3M Unitek Corporation K102803
Indications for use	Edgewise and Roth Ceramic Brackets are intended for use in orthodontic treatments. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Edgewise and Roth Ceramic Brackets are intended for use in orthodontic treatments. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Clarity Advanced Ceramic Brackets are intended for use in orthodontic treatments. The brackets are affixed to teeth so that pressure can be exerted on the teeth.
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction
Anatomical Site	Teeth	Teeth	Teeth
Location of use	Use only by professional orthodontists	Use only by professional orthodontists	Use only by professional orthodontists
Materials	Aluminum oxide	Aluminum oxide	Aluminum oxide
Biocompatibility	Aluminum oxide is medical grade and is accepted for ceramic brackets	Aluminum oxide is medical grade and is accepted for ceramic brackets	Aluminum oxide is medical grade and is accepted for ceramic brackets
Compatibility with the environment and other devices	Aluminum oxide is medical grade and is accepted for ceramic brackets	Aluminum oxide is medical grade and is accepted for ceramic brackets	Aluminum oxide is medical grade and is accepted for ceramic brackets
Sterility	Non-sterile	Non-sterile	Non-sterile
Maxillary In-out (mm)	0.94	0.6-1.2	0.53-.089
Maxillary Torque	0	-7 to +8	-7 to +17
Maxillary Angulation	0	0 to +12	0 to +8
Mandibular In-out (mm)	0.94	0.6 – 1.2	0.51-1.14
Mandibular Torque	0	-22 to 0	-17 to 0
Slot	0.022"	0.022"	0.022"

Substantial Equivalence

Both the non-clinical data and the biocompatibility evaluation indicate that Edgewise and Roth Ceramic Brackets are safe and effective for their intended use in orthodontic treatment and perform as well as the predicate.
The subject and predicate devices have the same intended use, indications for use, compositions, device design and performance.

Device Material and Design

The body of the subject and predicate devices are composed of ceramic. The Edgewise and Roth Ceramic Bracket is not coated and does not have a liner. The Morelli Brackets have rounded edges and corners. The Edgewise and Roth Ceramic Bracket is not built to facilitate debonding.

Conclusion

This premarket notification is being submitted to request clearance for the Edgewise and Roth Ceramic Brackets. The analysis on the Edgewise Ceramic Brackets demonstrates substantial equivalence to the 3M Unitek Corporation predicate.

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

August 27, 2013

Dental Morelli Limited
C/O Ms. Tara Conrad
Regulatory Affairs Manager
Techlink International Consultants
18851 NE 29th Avenue Suite 720
AVENTURA FL 33180

Re: K131197
Trade/Device Name: Edgewise Ceramic Brackets; Roth Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: May 15, 2013
Received: June 4, 2013

Dear Ms Conrad:

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 Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131197

Indications for Use Statement

Edgewise and Roth Ceramic Brackets are intended for use in orthodontic treatments. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Perscription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Sheena A. Green -S
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for M. Susan Runner, DDS, MA

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

510(k) Number: K131197

Concurrence of CDRH, Office of Device Evaluation
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