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,

Mary S. Runner -S

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Sheena A. Green -S
2013.08.27 14:29:58 -04'00'

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
(ODE) Page 1 of 1

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
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Sincerely yours,

Mary S. Runner -S

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

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K131197

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Myra Browne
Branch Chief Sign-Off	Sheena A. Green for M. Susan Runner, DDS, MA
Division Sign-Off	Mary S. Runner -S Susan Runner DDS, MA 2013.08.27 14:52:59 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Sheena A. Green -S
2013.08.27 14:29:58 -04'00'

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
(ODE) Page 1 of 1

K131197

Dental Morelli Ltda.

CONFIDENTIAL

COVER LETTER

April 15, 2013

Document Mail Center W066-G609
Center for Devices and Radiological Health Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002 – USA

RE: 510(k) Traditional Pre Market Notification Request

COMPANY NAME AND ADDRESS

DENTAL MORELLI LTDA
Alameda Jundiaí, 230 –
Jardim Saira - Sorocaba
CEP: 18085-090
Brazil

Telephone: 55 (15) 3238-8200

CONSULTANT NAME AND ADDRESS

TechLink International Consultants
18851 NE 29th Avenue
Suite 720
Aventura, Florida 33180

Telephone: (305) 377-0077

Primary Contact: Tara Conrad
Secondary Contact: Lilian Llull

Attention: Document Control Clerk

Device Trade Name:

Edgewise Ceramic Brackets
Roth Ceramic Brackets

According to Section 510 (k) of the Federal Food, Drug and Cosmetic Act, as amended (ACT), Dental Morelli Ltda proposes to introduce the Orthodontic Ceramic

MORELLI ORTODONTIA

Dental Morelli Ltda.

Brackets into interstate commerce for commercial distribution and hereby requests 510 (k) clearance by the Food and Drug Administration, as required by law.

The following information on these products (according to 21 CFR 807.87) is submitted for your consideration.

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

The eCopy is an exact duplicate of the paper copy.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?		✓
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?		✓

The predicate device and proposed device have the same intended use, same indications, and are designed with the same technological characteristics. A complete list of indications and a comparison table are included in Section 13. Indications for Use Statement can be found in Section 5. Labeling specifications are detailed in section 14. Considering our intent to market these devices, all information submitted is confidential; with the exception of the 510(k) summary.

Dental Morelli has not submitted prior applications for the same device. However, there are other manufacturers who have submitted 510(k) applications for similar devices. These similar devices are approved by the FDA. In particular the Clarity Advanced Ceramic Brackets that has been used as a predicate.

We are confident that this information will be sufficient for you to reach a favorable decision. However, please do not hesitate to contact me if you have any additional questions, concerns, or if you feel that I can be of any further assistance.

Best regards,

Tara Conrad, Biomedical Engineer
Regulatory Affairs Manager

(305) 377-0077 – ph
taraconrad@techlinkusa.net

Confidential

Table of Contents

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
4/18/2013	(b)(4)Trade Secret P	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Dental Morelli	Pending		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	55 (15) 3238-8200		
Street Address	FAX Number *(including area code)*		
Alameda Jundiai, 230/250			
City	State / Province	ZIP/Postal Code	Country
Sorocaba	Sao Paulo	18085-090	Brazil

(b)(4)Trade Secret Process

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
TechLink International Consulting			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	305-377-0077		
Street Address	FAX Number *(including area code)*		
18851 NE 29th Ave 720			
City	State / Province	ZIP Code	Country
Aventura	Florida	33180	USA
Contact Name			
Tara Conrad			
Contact Title	Contact E-mail Address		
Regulatory Affaris Manager	taraconrad@techlinkusa.net		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NJM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K102803	Clarity Advanced Ceramic Brackets	3M Unitek Corporation
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Orthodontic Ceramic Brackets

	Trade or Proprietary or Model Name for This Device	Model Number
1	Edgewise Ceramic Brackets	
2	Roth Ceramic Brackets	
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NJM	872.5470	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Dental		

Indications *(from labeling)*

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.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title		Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title		Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title		Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	N/A	FDA	Format for Traditional and Abbreviated 510 (k)'s	N/A	8/12/2005
2	ISO 10993-1	International Standards Organization	Biological evaluation of medical Part 1: Evaluation and testing		01/01/2009
3	ISO 14971	International Standards Organization	Medical Devices- application of risk management to medical		01/01/2007
4	ISO 15223-1	International Standards Organization	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements		01/01/2012
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved OMB No. 0910-511 Expiration Date February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

DENTAL MORELLI LTDA.
ALAMEDA JUNDIA,230/250
JD.SAIRA
SOROCABA / SP 18085-090
BR

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Roger Morelli
2.1 E-MAIL ADDRESS
assuntosregulatorios@morelli.com.br
2.2 TELEPHONE NUMBER (include Area code)
55-15-32388200
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD135206

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 25-Feb-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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COVER LETTER

April 15, 2013

Document Mail Center W066-G609
Center for Devices and Radiological Health Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002 – USA

RE: 510(k) Traditional Pre Market Notification Request

COMPANY NAME AND ADDRESS

DENTAL MORELLI LTDA
Alameda Jundiaí, 230 –
Jardim Saira - Sorocaba
CEP: 18085-090
Brazil

Telephone: 55 (15) 3238-8200

CONSULTANT NAME AND ADDRESS

TechLink International Consultants
18851 NE 29th Avenue
Suite 720
Aventura, Florida 33180

Telephone: (305) 377-0077

Primary Contact: Tara Conrad
Secondary Contact: Lilian Llull

Attention: Document Control Clerk

Device Trade Name:

Edgewise Ceramic Brackets
Roth Ceramic Brackets

According to Section 510 (k) of the Federal Food, Drug and Cosmetic Act, as amended (ACT), Dental Morelli Ltda proposes to introduce the Orthodontic Ceramic

Brackets into interstate commerce for commercial distribution and hereby requests 510 (k) clearance by the Food and Drug Administration, as required by law.

The following information on these products (according to 21 CFR 807.87) is submitted for your consideration.

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

The eCopy is an exact duplicate of the paper copy.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?		✓
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?		✓

The predicate device and proposed device have the same intended use, same indications, and are designed with the same technological characteristics. A complete list of indications and a comparison table are included in Section 13. Indications for Use Statement can be found in Section 5. Labeling specifications are detailed in section 14. Considering our intent to market these devices, all information submitted is confidential; with the exception of the 510(k) summary.

Dental Morelli has not submitted prior applications for the same device. However, there are other manufacturers who have submitted 510(k) applications for similar devices. These similar devices are approved by the FDA. In particular the Clarity Advanced Ceramic Brackets that has been used as a predicate.

We are confident that this information will be sufficient for you to reach a favorable decision. However, please do not hesitate to contact me if you have any additional questions, concerns, or if you feel that I can be of any further assistance.

Best regards,

Tara Conrad, Biomedical Engineer
Regulatory Affairs Manager

(305) 377-0077 – ph
taraconrad@techlinkusa.net

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

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

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

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.

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SECTION 7

Premarket Notification Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]
In my capacity as Director of Dental Morelli Ltda., I certify that to the best of my knowledge all data and information submitted in the premarket notification for the Edgewise and Roth Ceramic Brackets is truthful and accurate and that no material fact has been omitted.

Roger Morelli

Name: Roger Morelli
Position: Director
Date: 3/20/13

(Premarket Notification 510(k) number pending)

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SECTION 8

CLASS III SUMMARY AND CERTIFCATION

Edgewise and Roth Ceramic Brackets are class II devices.

This section does not apply.

CONFIDENTIAL

SECTION 9

FINANCIAL DISCLOSURE

Edgewise and Roth Ceramic Brackets are class II devices.

This submission is a traditional 510(k). A Clinical Trial was not conducted. The requirement for financial certification or disclosure as described in 21 CFR 807.87(i) does not apply to this submission.

Confidential

Section 10

Declaration of Conformity

Edgewise Ceramic Brackets
Roth Ceramic Brackets

Compliance with Performance Standards:

- ISO 10993-1:2009 - Biological evaluation of medical Part 1: Evaluation and testing
- ISO 14971:2007 - Medical devices - Application of risk management to medical
- ISO 15223-1:2012 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1: Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied -Part 1: Ge

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971 Medical Devices -Application of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2009 Biological evaluation of medical devices --Part 1: Evaluation and testing within a risk management process

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

BS EN ISO 27020: 2010: Dentistry. Brackets and tubes or use in orthodontics

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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SECTION 11

EXECUTIVE SUMMARY

Edgewise Ceramic Brackets
Roth Ceramic Brackets

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 brackets are uncoated. The Morelli brackets are not self-bonding and require a primer and adhesive to bond the bracket to the teeth. The Edgewise and Roth Ceramic Bracket are composed of aluminum oxide. These devices are designed for orthodontic use only. They are single use devices and are not to be reused.

Prescriptions	Model	Torque (°)		Angle (°)		In-out (mm)		With hook	No hook	Slot
		S	I	S	I	S	I			
Roth		+5	-	+12	-	0,7	-	-	1	.022″
		+8	-	+9	-	1,2	-	-	2	
		0	0	0	0	1,2	1,2	-	1,2	
		-2	-11	+9	+7	0,6	0,6	3	-	
		-2	-11	+13	+7	0,6	0,6	3	-	
		-7	-17	0	0	0,6	0,6	4	-	
		-7	-22	0	0	0,6	0,6	5	-	
Edgewise		0		0		0,94		-	1	.022″

Raw Material

(b)(4)Trade Secret Process

[redacted]

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.

Substantial Equivalence

Both the non-clinical data and the biocompatibility evaluation indicate that Edgewise and Roth Ceramic Brackets are safe and effective for they intended use in orthodontic treatment and perform as well or better than the predicated. The subject and predicate devices have the same intended use, indications for use, compositions, device design and performance. Further details can be observed in the table below:

	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”

Summary of Performance Testing

The Edgewise and Roth Ceramic Brackets materials were evaluated according to ISO 10993-1. The results of this test confirmed that the Morelli Ceramic Brackets met the biomaterial compatibility requirements. A detailed test report can be seen in Section 20 of this submission.

CONFIDENTIAL

SECTION 12

Device Description

Edgewise Ceramic Bracket
Roth Ceramic Bracket

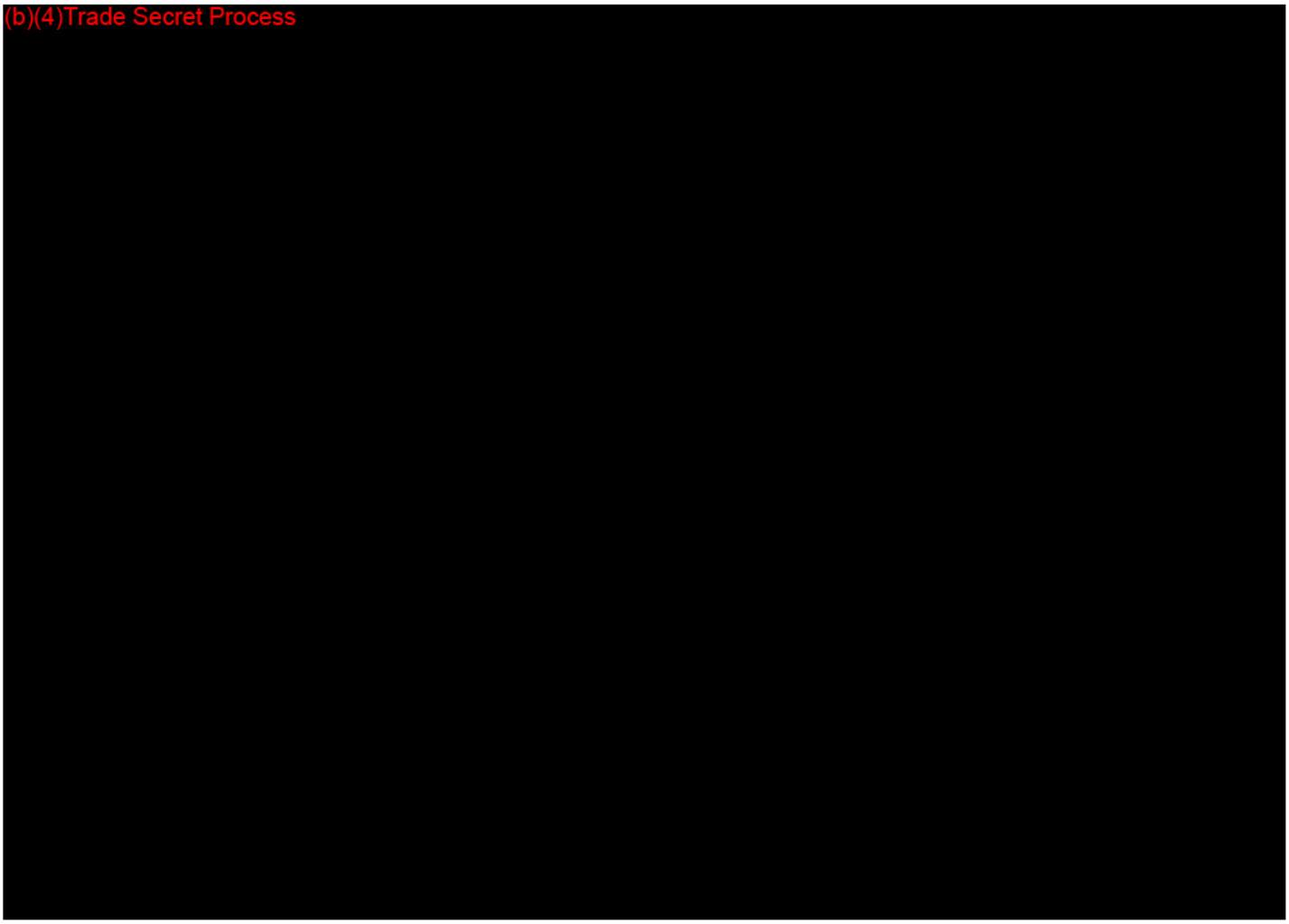
Description of Proposed Device

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. [redacted] (b)(4)Trade Secret Process

The Morelli bracket is manufactured using and injection-molding process. This process produces a stronger bracket than machining the bracket. (b)(4)Trade Secret Process [redacted] rounded edges on the brackets instead of square edges seen on machined brackets. The Edgewise Ceramic Bracket is composed of aluminum oxide.

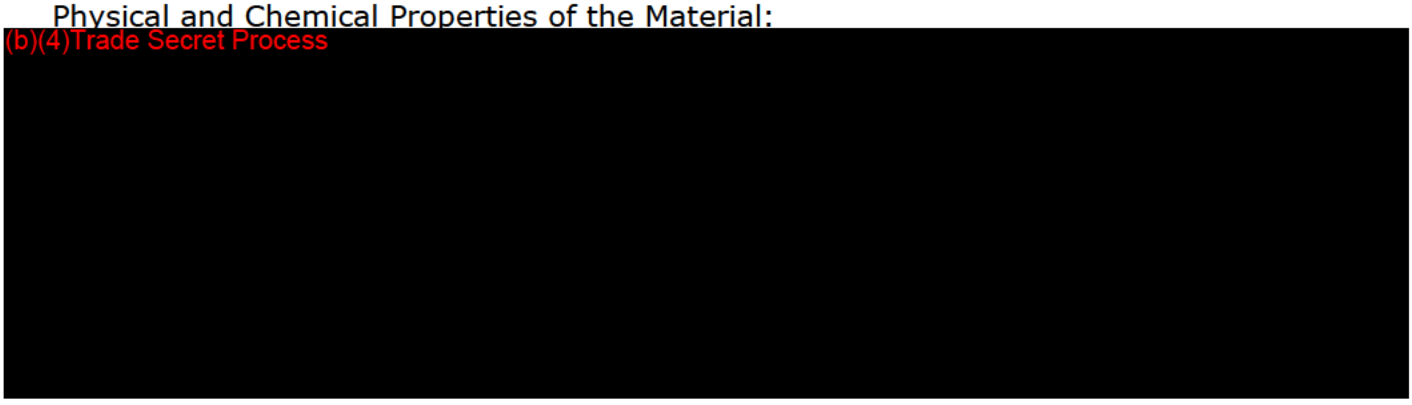
(b)(4)Trade Secret Process [redacted]

(b)(4)Trade Secret Process



Physical and Chemical Properties of the Material:

(b)(4)Trade Secret Process



Material

(b)(4)Trade Secret Process

Packaging

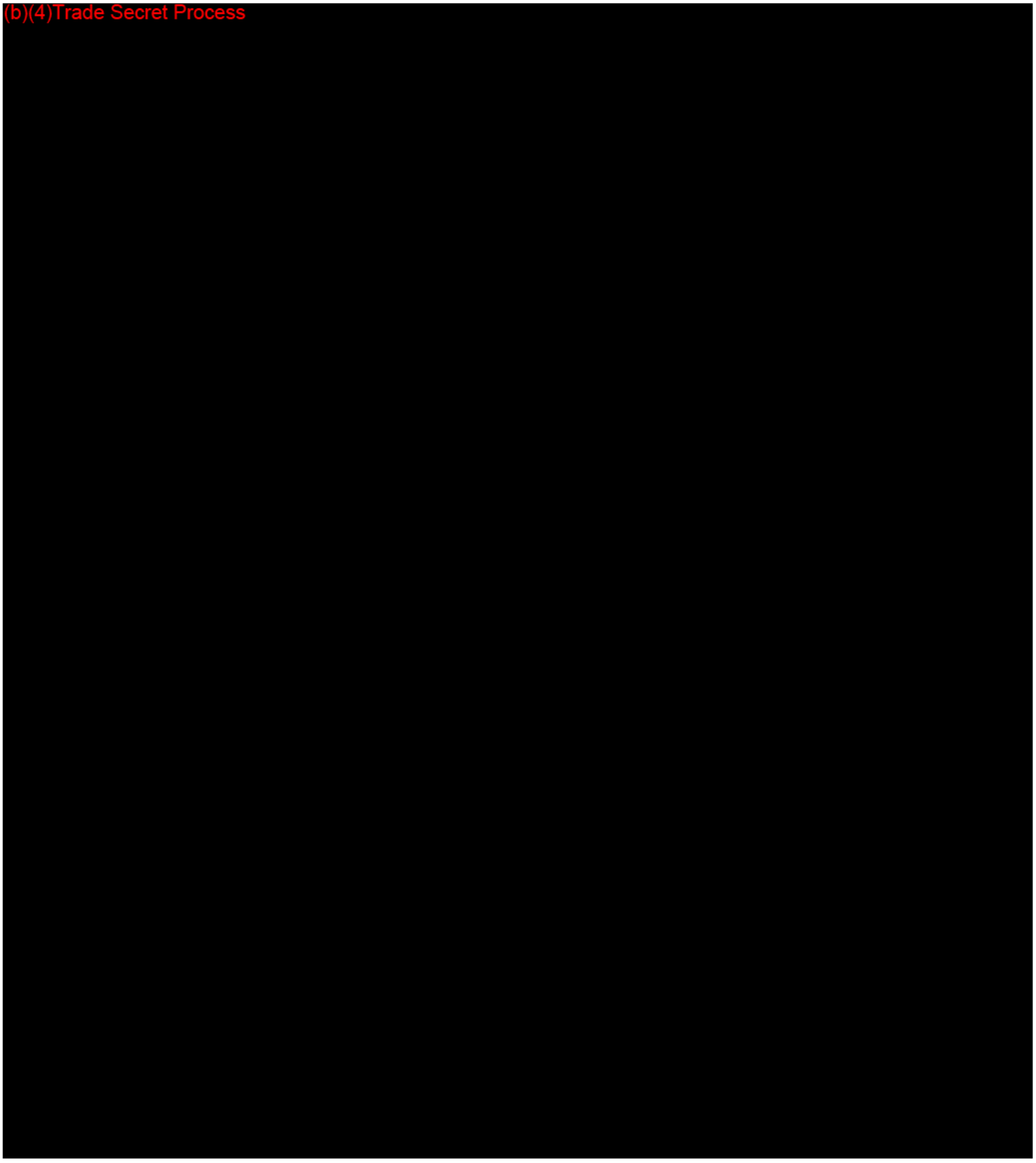
The requirements of brackets and tubes are differentiated by a colored stripe on the packaging:

Technique	Color stripe
Roth	
Edgewise	

A more detailed explanation can be found in section 15-Proposed Labeling.

Cleaning Process

(b)(4)Trade Secret Process



MSDS

Identification of the Product

1. Identification of the substance/preparation and of the company/undertaking;

1.1- Identification of the substance/preparation;

Aluminium Oxide Ceramic Products.

1.2- Identification of the of the company / undertaking;

Dental Morelli Ltda.
Alameda Jundiaí, 230 / 250
Jardim Saira
ZIP 18085-090 – Sorocaba – São Paulo – Brazil.
Technical responsible: Eng. Roger. Roger Morelli

Emergency telephone number of the company and / or official advisory body in accordance with Article 12 of Directive 88/379/EEC.

In Brazil:
+55 (15) 0800-141255
+55 (15) 3238-8200
In Europe:
EUROPEAN REPRESENTATIVE
Nuno Flores
Al. Bonifácio Lázaro Lozano, 3 - Piso 0 - C
2780-125 Oeiras - Portugal
info.morelli@euroconexao.com
Tel. +351 214439292 / Fax +351 214439294
In USA:
Mr. Yesid Arias Urrea
ariasint@bellsouth.net
Phone: 1-954 2362788

2. Composition/information on ingredients;

Aluminum oxide - Al_2O_3.
CAS no. 1344-28-1.

3. Hazards identification;

The information of this document if they refer to the product in your supply condition. This product is not considered dangerous, however it is possible the accidental inhalation or ingestion of parts or fragments during the use.
Eventual grinding or cut operations can generate dangerous powders.

4. First-aid measures;

In case of inhalation seek a doctor.
In the case of powder inhalation, to move the patient for place with fresh air and to seek a doctor.

5. Fire-fighting measures;

Not inflammable material.

6. Accidental release measures;

To clean the place.
To observe the directives and effective laws.

7. Handling and storage;

7.1 Handling;

Handling foreseen by capable and qualified professionals.

7.2 Storage;

To maintain in the original packing until the moment of use.

8. Exposure controls/personal protection;

Use good work practices; gloves and masks.

9. Physical and chemical properties;

Solid material.
Translucent color.
Insoluble in water.
Odorless.

10. Stability and reactivity;

Stable material in conditions of supply.

11. Toxicological information;

Not hazardous material.

12. Ecological information;

Any ecological effect is not known.
To observe the directives and effective laws.

13. Disposal considerations;

Use good biosafety practices.
To observe the directives and effective laws.

14. Transport information;

Transports in a safety way for do not damage the package.

15. Regulatory information;

Attempt to good work practices.
Material intended for use by qualified professionals.

16. Other information.

The document's information is based on the knowledge obtained until the present date and it is intended to a description of the product regarding its safety measures.
This description does not ensure the product's properties or characteristics.
The Dental Morelli Ltd., has rights reserved on doing technical alterations in technical specifications, with no prior advertising.

Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

CONFIDENTIAL

SECTION 13

SUBSTANTIAL EQUIVALENCE DISCUSSION

Edgewise Ceramic Brackets
Roth Ceramic Brackets

CLAIMING SUBSTANTIAL EQUIVALENCE WITH:

Device Name: Clarity Advance Ceramic Brackets
Manufacturer: 3M Unitek Corporation
K Number: K102803

	Edgewise Ceramic Brackets by Dental Morelli	Roth Ceramic Brackets by Dental Morelli	Clarity Advance Ceramic Brackets by 3M Unitek Corporation K102803	Differences
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	The differences do not propose and safety or effectiveness concerns. Differences are expected as each manufacturer designs their devices to meet as many patients needs
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	

				as possible. The differences are between the accepted values allowed for these types of devices.
Slot	0.022”	0.022”	0.022”	

The difference between the prescriptions is summarized in angulations, torque, in-out of the brackets that per action promoted by orthodontic arches results in correction of malocclusion. The orthodontist chooses the prescription that gives best results.

Dental Morelli chose manufactured ceramic brackets in the prescriptions already developed: Straight-Wire Prescription (Edgewise) and Roth Prescription.

Ceramic Brackets follow constructive characteristics of torque, angle, in-out described in BS EN ISO 27020:2010 Dentistry – Brackets and tubes for use in orthodontics.

Therefore, the differences between the prescriptions subject and predicate devices are torque, angle, in-out and length.

The application of the Brackets prescriptions is the same, the orthodontist decide what will be the best prescription to be applied to the treatment of each patient.

The maxillary in-out, maxillary torque, maxillary angulation, mandibular in-out and mandibular torque all have slight variances from the predicate. The small variances do not affect the safety or effectiveness of the subject devices. The subject devices are well within the standard of acceptance for the roth and edgewise ceramic brackets.

Predicate Device Information

K102803 Clarity Advanced Ceramic Brackets

Clarity™ ADVANCED Ceramic Brackets A Technical Perspective

by Nicole Wagner, Bill Wyllie, and Glenys Thorstenson

Nicole Wagner is a Senior Technical Service Engineer at 3M Unitek. She received her B.S. in Chemistry from the State University of New York at Stony Brook. Her M.S. and Ph.D. are in Mechanical Engineering from the University of Minnesota, where her research focused on synthesis, characterization, and reaction modeling of hard, wear-resistant ceramic materials. She has been at 3M since 2007, joining 3M Unitek in 2010.

Bill Wyllie is a Product Development Specialist at 3M Unitek. He is active in the development of new aesthetic materials for brackets, and has worked on a variety of product development teams such as SmartClip™ and Clarity™ SL Self-Ligating Brackets and Forsus™ Class II Correctors. He received his B.S. in Materials and Metallurgical Engineering from the University of Michigan and his M.S. and Ph.D. in Materials Engineering from Rensselaer Polytechnic Institute. He has been at 3M Unitek since 1997.

Glenys Thorstenson received her B.S. in Materials Science and Engineering from Michigan State University and her Ph.D. in Biomedical Engineering from the University of North Carolina at Chapel Hill. Her dissertation focused on the resistance to sliding of novel orthodontic bracket systems. She has been at 3M Unitek since 2003.

Introduction

As more patients seek a more aesthetic orthodontic treatment, orthodontists still demand functionality in their orthodontic appliances. Through various discussions with orthodontists and assistants, the 3M Unitek product development team assessed that ceramic brackets need to maintain the characteristics of aesthetics, small physical size, strength, predictable debonding, and a design that is comfortable to patients. New Clarity™ ADVANCED Ceramic Brackets incorporate these features into a revolutionary design to give orthodontists the aesthetics and efficiency they require.

Bracket Material and Design

Advances in materials, manufacturing technologies, and bracket design have enabled new levels of performance in the Clarity brand of aesthetic brackets. Clarity ADVANCED Ceramic Brackets are made of polycrystalline alumina, which consists of small crystals, called "grains" (Figure 1A-B). As the size of these grains decreases, the strength of the ceramic material increases (Figure 2). Clarity ADVANCED Brackets are made of the same material

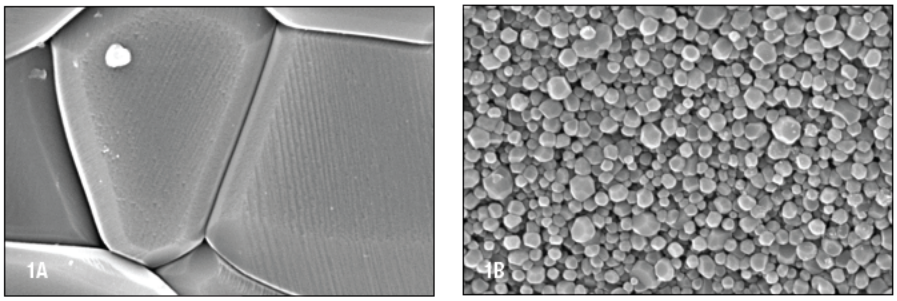


Figure 1A-B Average alumina grain size of (A) 15 µm (Clarity™ Metal-Reinforced Ceramic Bracket) and (B) 0.9 µm (Clarity™ ADVANCED Ceramic Bracket).

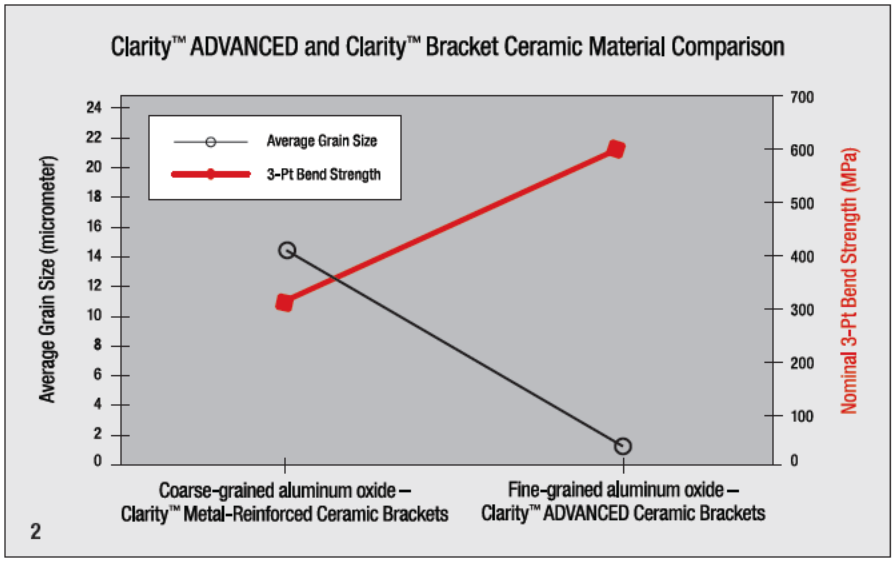


Figure 2 As average grain size decreases, strength of material increases.

as that used in Clarity™ SL Self-Ligating Brackets, which is a finer-grained ceramic than the leading polycrystalline ceramic brackets. In addition, the finer grain size of the ceramic material in Clarity™ ADVANCED Ceramic Brackets improves its inherent material strength as compared to the material used in Clarity brackets. Therefore, as seen in tie-wing crush strength testing, while overall smaller in size, the strength of the Clarity ADVANCED brackets is comparable to Clarity brackets. Also, since the material is the same as that used in Clarity SL brackets, the material is proven to resist staining to various staining agents throughout the course of treatment. In addition, the translucent material of the Clarity ADVANCED brackets blends with the color of various tooth shades.

Clarity ADVANCED brackets are fabricated by an injection-molding process. This method permits the creation of smooth, rounded corners designed to reduce binding and notching at the bracket slot corners. Binding is an element of friction that contributes to the resistance to sliding when the archwire is in contact with the corners of the bracket slot. It is impacted by the materials and geometries of the archwires and brackets, and does not depend on the force applied by the ligature[1].

Another factor that contributes to friction is notching, which is the resistance to sliding when the bracket permanently deforms the archwire. Most often, notching is due to the ligature force and occurs on the lingual side of the archwire. However, notching can also occur on the occlusal or gingival sides[2]. Images of bracket slot corners of Clarity ADVANCED brackets and other ceramic brackets that are currently on the market are shown in Figure 3A-D. The bracket slot corners of the Clarity ADVANCED brackets appear to be more rounded and smooth compared to the other ceramic brackets.

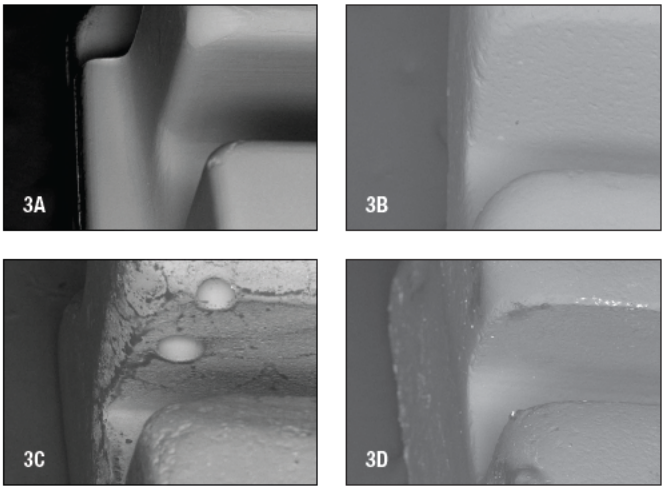


Figure 3A-D Bracket slot corners of (A) 3M Unitek Clarity™ ADVANCED, (B) American Radiance™, (C) GAC Mystique™, and (D) Ormco Inspire ICE™ Brackets.

To allow for an increased inter-bracket distance, Clarity ADVANCED brackets are designed to have small mesio-distal dimensions. For reduced occlusal interference, Clarity ADVANCED brackets have small occlusal-gingival dimensions. In addition, Clarity ADVANCED brackets feature a generous under-tie-wing area to allow for both single- and double-ligation. Of the doctors surveyed during a ligation study (3M Unitek), 91% found that the Clarity ADVANCED brackets easily accommodate double-ligation.

Bonding Base and Predictable Debonding

The bonding base of Clarity ADVANCED brackets has been designed with a tooth-specific anatomy, similar to Clarity and Clarity SL brackets, to contour to the shape of patients' teeth and provide a better fit to each tooth. Also, similar to Clarity and Clarity SL brackets, Clarity ADVANCED brackets have a micro-crystalline surface on the base to create a mechanical bond with the adhesive (Figure 4).

Figure 4
Clarity™ ADVANCED Ceramic Bracket bonding base with stress-concentrator.

To maintain the predictable debonding that orthodontists are accustomed to with the Clarity brand of brackets, the new Clarity ADVANCED ceramic brackets also feature the proprietary stress-concentrator vertically along their bracket base (Figure 4). When debonding a bracket, the adhesive first breaks at the edge of the bracket, initiating a crack that continues through the adhesive layer along the bracket base, after which the stress-concentrator collapses the bracket vertically in half[3]. With a mesial-distal 'rocking' motion, first towards the half of the bracket where the adhesive first broke, then towards the other half, the Clarity ADVANCED bracket can be removed entirely from the tooth. The recommended debonding tool is the same as that used for Clarity SL brackets, namely the Unitek™ Self-Ligating Bracket Debonding Instrument. To remove a bracket, this instrument is inserted in the labial side of the bracket with the instrument blade along the vertical

center slot and its ledges seated on the tie-wings. Using the mesial-distal squeeze debonding technique, Clarity™ ADVANCED Ceramic Brackets can be debonded on or off the archwire (Figure 5A-B). When debonding on the archwire, the ligature supports the collapsed bracket halves. Care should be taken to grasp and hold the collapsed bracket when debonding off the archwire.

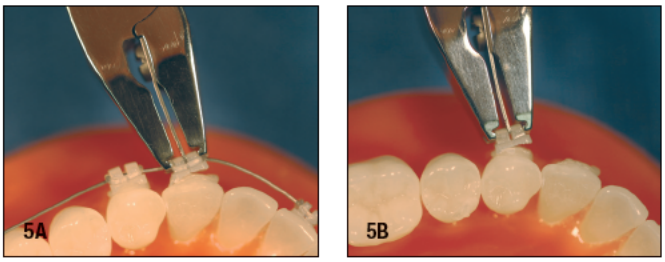


Figure 5A-B Debonding Clarity™ ADVANCED Ceramic Brackets using the Unitek™ Self-Ligating Bracket Debonding Instrument either (A) on or (B) off the archwire.

Patient Comfort

Clarity ADVANCED brackets are designed to provide enhanced patient comfort. By using an injection-molding process, smooth, rounded corners are created. The dome-shaped design and rounded bi-directional ball hooks are intended to further improve patient comfort.

The low profile design of Clarity ADVANCED brackets aims to provide patients with enhanced comfort. In addition, the low profile of lower anterior Clarity ADVANCED brackets reduces occlusal interference, giving orthodontists more flexibility to use ceramic brackets on a patient's lower arch. Clarity ADVANCED brackets have an in/out dimension that is compatible with that of Victory Series™ Low Profile Brackets.

Conclusions

Clarity ADVANCED brackets are a new generation of ceramic brackets with both aesthetics and functionality. The aesthetics of the bracket are enabled by its translucent fine-grained alumina material and low-profile design. The smooth, rounded features of the bracket can both reduce binding and notching during treatment and assist with increasing patient comfort. With these features and the predictable debonding that remains a key feature of the Clarity brand, the Clarity ADVANCED bracket system provides an excellent aesthetic solution for both patients and orthodontists.

References

1. Thorstenson GA, Kusy RP, "Effect of archwire size and material on the resistance to sliding of self-ligating brackets with second-order angulation in the dry state" *Am J Orthod Dentofacial Orthop* 2002; 122: 295-305.
2. Articolo LC, Kusy K, Saunders CR, Kusy RP, "Influence of ceramic and stainless steel brackets on the notching of archwires during clinical treatment" *Eur J Orthod* 2000; 22: 409-425.
3. Hansen J. "Ceramic Orthodontic Bracket with Debonding Channel" US Patent Number 5439379, 8 Aug 1995.

Reprinted from *Orthodontic Perspectives* Vol. XVIII No. 2.

Clarity™ ADVANCED Ceramic Brackets Parts List

CLARITY™ | ADVANCED
advanced ceramic brackets

Maxillary			IN/OUT		0.018 in. Slot		0.022 in. Slot	
Tooth	Torque	Angulation	in.	mm	L	R	L	R
Central	+17	+4	0.026	0.66	006-201	006-202	006-301	006-302
Lateral	+10	+8	0.035	0.89	006-205	006-206	006-305	006-306
Cuspid HK	0	+8	0.021	0.53	006-209	006-210	006-309	006-310
Universal Bicuspid	-7	0	0.029	0.74	006-211		006-311	
Mandibular			**IN/OUT**		**0.018 in. Slot**		**0.022 in. Slot**	
Tooth	Torque	Angulation	in.	mm	L	R	L	R
Anterior	-6	0	0.045	1.14	006-250		006-350	
Cuspid HK	0	+3	0.020	0.51	006-253	006-254	006-353	006-354
1st Bicuspid	-12	+2	0.030	0.76	006-255	006-256	006-355	006-356
2nd Bicuspid	-17	+2	0.034	0.86	006-259	006-260	006-359	006-360
					Adding Prefix "3" is APC™ II Adhesive System			
					Adding Prefix "5" is APC™ PLUS Adhesive System			

Single Patient Kits	0.018 in. Slot	0.022 in. Slot
U/L 5x5 Clarity™ ADVANCED Brackets Cuspid HK	006-100	006-110
U/L 3x3 Clarity ADVANCED Brackets Cuspid HK	006-103	006-113
U 5x5 Clarity ADVANCED Brackets Cuspid HK	006-105	006-115
U 3x3 Clarity ADVANCED Brackets Cuspid HK	006-108	006-118
	Adding Prefix "3" is APC II Adhesive System	
	Adding Prefix "5" is APC PLUS Adhesive System	

APC™ II
Available in APC™ II Adhesive Coated Appliance System

APC™ PLUS
Available in APC™ PLUS Adhesive Coated Appliance System

MBT™
Versatile+ Appliance System

3M Unitek

Clarity™ ADVANCED Ceramic Brackets
Practice Marketing Tools

CLARITY™ | ADVANCED
advanced ceramic brackets

Description	Part Number
Bracket Typodont	600-236
20x Demonstration Model	600-237
Patient Brochure - Large	021-118
Patient Brochure - Small	021-119
Lenticular - Comparison With Metal Braces	012-255
Desktop Display (11x8.5 in.) - Group	014-536
Desktop Display (8.5x11 in.) - Blonde Woman	014-537
Desktop Display (8.5x11 in.) - Brunette Woman	014-538
Desktop Display (8.5x11 in.) - Dark Hair Woman	014-539
Desktop Display (8.5x11 in.) - Male	014-540
Office Poster (24x18 in.) - Group	014-541
Office Poster (18x24 in.) - Blonde Woman	014-542
Office Poster (18x24 in.) - Brunette Woman	014-543
Office Poster (18x24 in.) - Dark Hair Woman	014-544
Office Poster (18x24 in.) - Male	014-546

For product and model images to use in your practice marketing, contact 3M Unitek at 800-423-4588 and ask for extension 4303.

Desktop Displays/Office Posters

3M
3M Unitek
Orthodontic Products
2724 South Peck Road
Monrovia, CA 91016 USA
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Technical Helpline: 1-800-265-1943 • 626-574-4577
CE Hotline: 1-800-852-1990 x4649 • 626-574-4649
Outside these areas, contact your local representative.

012-261-1 1204

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SECTION 14

PROPOSED LABELING

Edgewise Ceramic Brackets

Roth Ceramic Brackets

The requirements of brackets and tubes are differentiated by a colored stripe on the packaging:

Technique	Color stripe
Roth	
Edgewise	

Presentation forms of health product (including packaging, quantity and dimensions).

Product	Packaging Type	Quantity	Dimension
Kit	box	20 units	105mm (length) x 62mm (width) x 10mm (height)
Loose	blister	05 units	78mm (length) x 43mm (width) x 8mm (height)

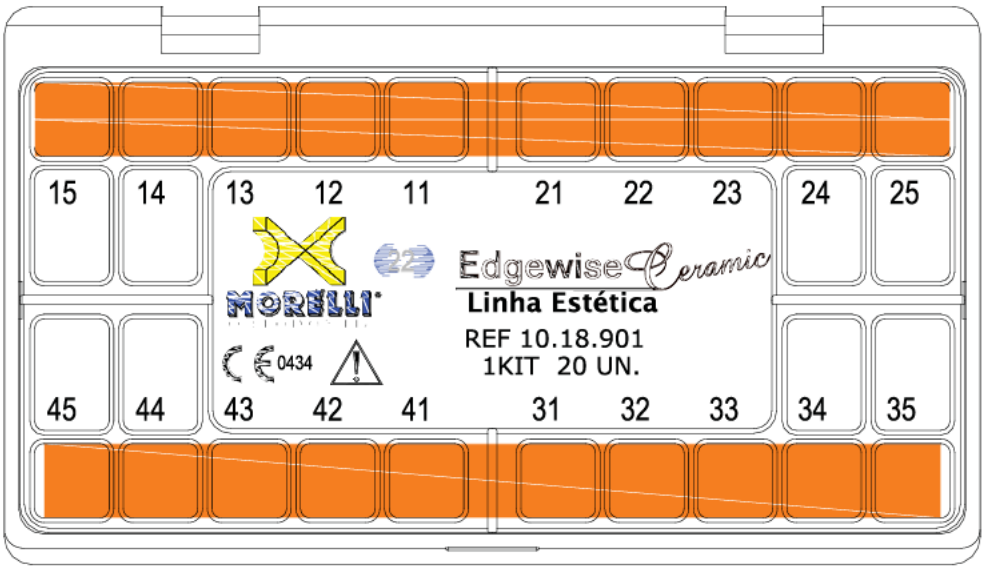
NOTE – The Kit is composed by specific brackets for each tooth; loose are similar parts used for replacement.

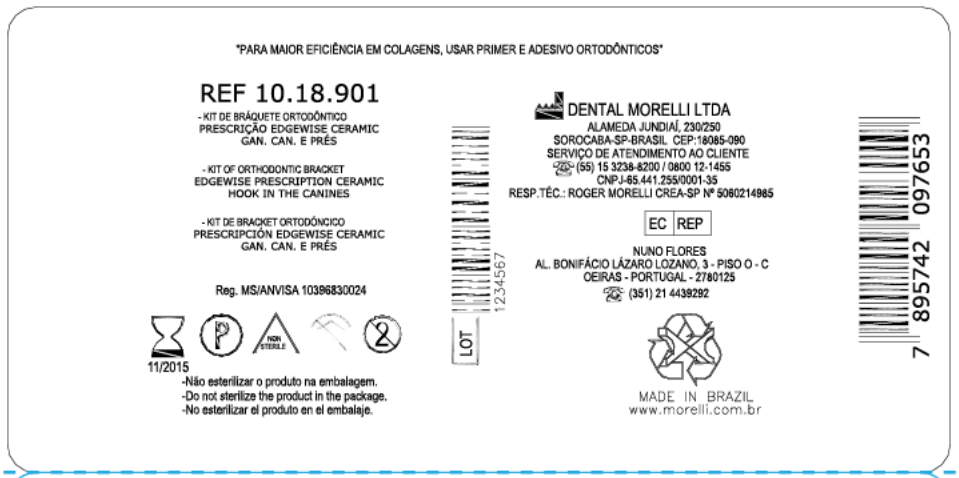
The requirements of brackets and tubes are differentiated by a colored stripe on the packaging:

Technique	**Color stripe**
Roth	
Edgewise	

The packaging of the kits for the positioning of the parts:

PACKAGING MODEL OF BRACKET KITS (BOX)





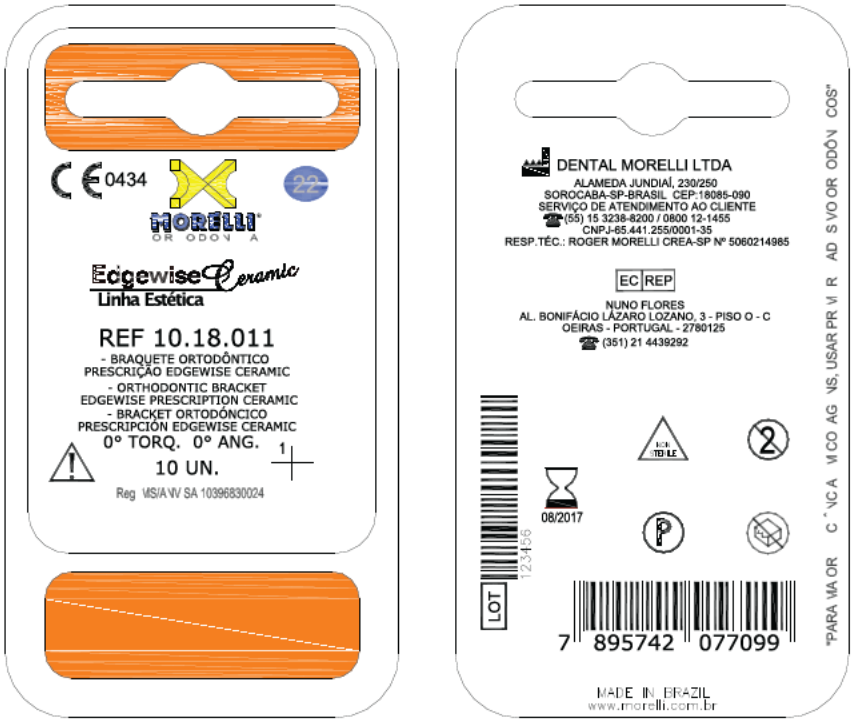
Fold down

1. Device Description- 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.

2. Rx Only

3. 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.

PACKAGING MODEL OF LOOSE BRACKETS
BLISTER



ICONS USED BY DENTAL MORELLI ON EXPANSION SCREWS COMPOSITE		
Legal company name and Organization address	Product registration number at the Ministry of Health / ANVISA	Code bar for product identification
CE Mark for medical devices class II and IIa* CE 0434	Data referring to the European Representative	Code bar for manufacturing lot identification
Lot number for traceability* LOT	European Representative EC REP	Product description and instructions for use in three languages
For exclusive use by the qualified professional**	Attention! Read the instructions for use *	Product expiration date (year/month)* 06-2011
Do not use the product if the packaging has been torn*	Product code related to the catalogue* REF	Non-reusable product*

Non-sterile product* 	Recycle 	Manufactured by 

The symbols employed vary according to the need under consideration of the technical characteristics of each product.

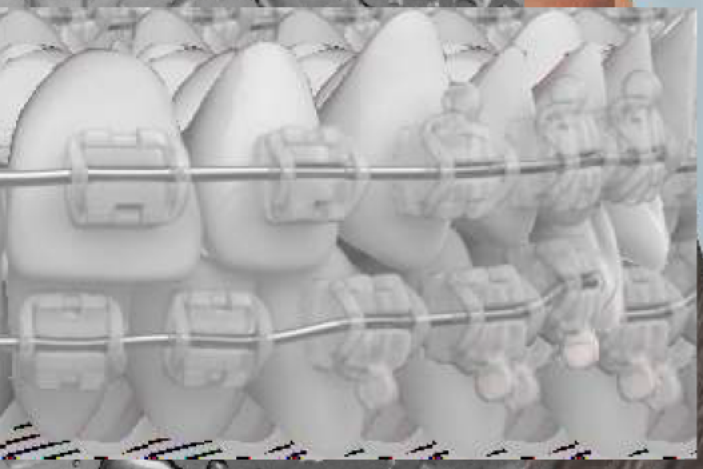
* Symbols employed in compliance with Harmonized Standards named herein (DIN EN 980 and ABNT NBR ISO 15223).
** Symbols adapted to complete the given information with the purpose of minimizing eventual risks inherent to the product use.

Edgewise Ceramic

Aesthetic line

MORELLI ORTODONTIA

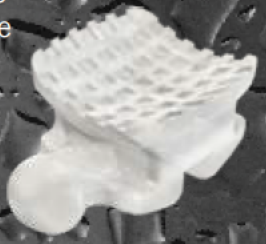
The orthodontic "Ceramic" brackets by Morelli incorporate beauty, functionality and strength into a sophisticated and sleek device.



The brackets are manufactured from a polycrystalline ceramic. The brackets are translucent, chemically stable, biocompatible, do not wear out or lose their color.

The design has been specially created to provide great comfort to the patient, emphasizing the rounded forms and low profile.

The base is produced of ridges in order to anatomically adhere to the cervico occlusal. This design allows for greater adhesion to the enamel without the undesirable removal effects.



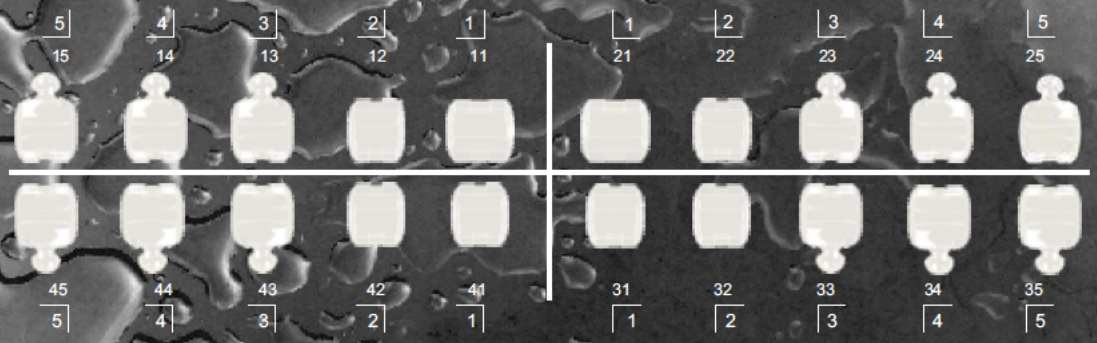
The Ceramic brackets offer a high degree of sliding, due the slot with rounding in the ends and the exclusive polishing process for ceramics. Thus, the free movement is ensured even under a important misalignment of teeth.

Edgewise Ceramic

Aesthetic line

Strength
Beauty
Discretion

Slot										
Length	3,2 mm	3,2 mm	3,2 mm	2,9 mm	3,6 mm	3,6 mm	2,9 mm	3,2 mm	3,2 mm	3,2 mm
Torq	0°	0°	0°	0°	0°	0°	0°	0°	0°	0°
Angle	0°	0°	0°	0°	0°	0°	0°	0°	0°	0°
In/out	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm
Replacements .022" x .030"	10.18.013	10.18.013	10.18.013	10.18.012	10.18.011	10.18.011	10.18.012	10.18.013	10.18.013	10.18.013



Slot										
Length	3,2 mm	3,2 mm	3,2 mm	2,9 mm	2,9mm	2,9 mm	2,9 mm	3,2 mm	3,2 mm	3,2 mm
Torq	0°	0°	0°	0°	0°	0°	0°	0°	0°	0°
Angle	0°	0°	0°	0°	0°	0°	0°	0°	0°	0°
In/out	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm	1,20 mm
Replacements .022" x .030"	10.18.013	10.18.013	10.18.013	10.18.012	10.18.012	10.18.012	10.18.012	10.18.013	10.18.013	10.18.013

The Morelli Ceramic Brackets are available through Morelli or over 150 distributors/re-salers throughout Brazil.

CB: 90.80.103

DENTAL MORELLI LTDA
Alameda Jundiaí, 230/250
Sorocaba - SP - Brasil - CEP: 18085-090
Serviço de atendimento ao cliente
(55) 15 - 3238-8200 / 0800 12-1455

MORELLI ORTODONTIA 100% Brasileira
www.morelli.com.br

Edgewise Ceramic
Aesthetic line

Rx Only

Device Description

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.

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SECTION 15

STERILIZATION AND SHELF LIFE

(b)(4)Trade Secret Process

[redacted]

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SECTION 16

BIOCOMPATIBILITY

(b)(4)Trade Secret Process

[redacted]

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SECTION 17

SOFTWARE VALIDATION

(b)(4)Trade Secret Process

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Section 18

Electromagnetic Safety

Edgewise Ceramic Brackets
Roth Ceramic Brackets

This section does not apply.

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SECTION 19

BENCH TESTING

Edgewise Ceramic Brackets
Roth Ceramic Brackets

(b)(4)Trade Secret Process - Bench Testing

(b)(4)Trade Secret Process - Bench Testing

(b)(4)Trade Secret Process - Bench Testing

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SECTION 20

ANIAML TESTING

Edgewise Ceramic Brackets
Roth Ceramic Brackets

The Edgewise and Roth Ceramic Brackets did not involve animal testing. This section does not apply.

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SECTION 21

CLINICAL TRIALS

Edgewise Ceramic Brackets
Roth Ceramic Brackets

This is a traditional 510(k) premarket clearance. Certification of Compliance under 42 U.S.C. does not apply.

The Edgewise and Roth Ceramic Brackets did not involve clinical trials. This section does not apply.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Dental Morelli LTDA

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Feb 6, 2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Alameda Jundiai, 230-
Jardim Saira-Sorocaba
CEP: 18085-090
Brazil

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 55 15 3238-8200
(Fax)

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Edgewise Ceramic Brackets

Roth Ceramic Brackets

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
N/A

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
N/A

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Lilian Glull
(Title) Senior Partner

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
18851 NE 29th Ave Suite 720
Aventura FL 33180

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 305.377.0077
(Fax)

15. DATE OF CERTIFICATION
3/28/13

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

Barlow, Lenny *

From: Barlow, Lenny *
Sent: Thursday, August 29, 2013 3:45 PM
To: 'taraconrad@techlinkusa.net'
Cc: DCCLetters
Subject: k131197 Correspondence
Attachments: k131197.pdf

Tracking:

Recipient	Delivery
'taraconrad@techlinkusa.net'	
DCCLetters	Delivered: 8/29/2013 3:45 PM

5

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Myra E. Browne

Subject: 510(k) Number K131197

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)		X
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)	X	
Adolescent (12 years to <18 years)	X	
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

gulation Number:	872.5470
Class:	II
Product Code:	NJM
Additional Product Codes:	

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Sheena A. Green -S 2013.08.27 14:27:54 -04'00'
Division Sign-Off	Susan Runner DDS, MA Mary S. Runner -S 2013.08.27 14:49:28 -04'00'

K131197/S001

Dental Morelli Ltda.

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COVER LETTER

April 15, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002 – USA

RE: 510(k) Traditional Pre Market Notification Request

COMPANY NAME AND ADDRESS

DENTAL MORELLI LTDA
Alameda Jundiaí, 230 –
Jardim Saira - Sorocaba
CEP: 18085-090
Brazil

Telephone: 55 (15) 3238-8200

CONSULTANT NAME AND ADDRESS

TechLink International Consulting
18851 NE 29th Avenue
Suite 720
Aventura, Florida 33180

Telephone: (305) 377-0077

Primary Contact: Tara Conrad
Secondary Contact: Lilian Llull

Attention: Document Control Clerk

Device Trade Name:

Edgewise Ceramic Brackets
Roth Ceramic Brackets

According to Section 510 (k) of the Federal Food, Drug and Cosmetic Act, as amended (ACT), Dental Morelli Ltda proposes to introduce the Orthodontic Ceramic

Brackets into interstate commerce for commercial distribution and hereby requests 510 (k) clearance by the Food and Drug Administration, as required by law.

The following information on these products (according to 21 CFR 807.87) is submitted for your consideration.

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

The eCopy is an exact duplicate of the paper copy.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?		✓
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?		✓

MORELLI
ORTODONTIA

Dental Morelli Ltda.

The predicate device and proposed device have the same intended use, same indications, and are designed with the same technological characteristics. A complete list of indications and a comparison table are included in Section 13. Indications for Use Statement can be found in Section 5. Labeling specifications are detailed in section 14. Considering our intent to market these devices, all information submitted is confidential; with the exception of the 510(k) summary.

Dental Morelli has not submitted prior applications for the same device. However, there are other manufacturers who have submitted 510(k) applications for similar devices. These similar devices are approved by the FDA. In particular the Clarity Advanced Ceramic Brackets that has been used as a predicate.

We are confident that this information will be sufficient for you to reach a favorable decision. However, please do not hesitate to contact me if you have any additional questions, concerns, or if you feel that I can be of any further assistance.

Best regards,

Tara Conrad, Biomedical Engineer
Regulatory Affairs Manager

(305) 377-0077 – ph
taraconrad@techlinkusa.net

(b)(4)Trade Secret Process - Product Specs

(b)(4)Trade Secret Process - Product Specs

CONFIDENTIAL

COVER LETTER

April 15, 2013

Food and Drug Administration
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10903 New Hampshire Avenue
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RE: 510(k) Traditional Pre Market Notification Request

COMPANY NAME AND ADDRESS

DENTAL MORELLI LTDA
Alameda Jundiaí, 230 –
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Telephone: 55 (15) 3238-8200

CONSULTANT NAME AND ADDRESS

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18851 NE 29th Avenue
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Telephone: (305) 377-0077

Primary Contact: Tara Conrad
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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

The eCopy is an exact duplicate of the paper copy.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?		✓
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?		✓

The predicate device and proposed device have the same intended use, same indications, and are designed with the same technological characteristics. A complete list of indications and a comparison table are included in Section 13. Indications for Use Statement can be found in Section 5. Labeling specifications are detailed in section 14. Considering our intent to market these devices, all information submitted is confidential; with the exception of the 510(k) summary.

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Best regards,

Tara Conrad, Biomedical Engineer
Regulatory Affairs Manager

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