May 4, 2023

Orthometric - Industria e Comercio de Produtos Medicos
% Tatiana Botura
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Aem Saadi, 855/ 2402
Ribeirao Preto, SP 14096570
Brazil

Re: K222847
Trade/Device Name: Ceramic Brackets Orthometric
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: February 2, 2023
Received: February 3, 2023

Dear Tatiana Botura:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222847

Device Name
Ceramic Brackets Orthometric

Indications for Use *(Describe)*
Ceramic Brackets Orthometric are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510 (K) Summary K222847

ADMINISTRATIVE INFORMATION

Sponsor	Orthometric – Indústria e Comércio de produtos médicos e odontológicos LTDA Rua Irineu Martins, 280 – Distrito de Lacio – Marília, SP – Brazil
Contact Person and Preparer	Tatiana Jabor Botura and Bruno Milhoci Regulatory Affairs Specialist Passarini Regulatory Affairs E-mail: tatiana@passarini.com.br Telephone + 55 (16) 3421 8488
Date Prepared	04/13/2023

DEVICE NAME AND CLASSIFICATION

Trade Name	Ceramic Brackets Orthometric
Common Name	Orthodontic Ceramic Brackets
Regulation Number	21 CFR 872.5470
Regulatory Class	II
Product Code	NJM
Classification Panel	Dental

PREDICATE DEVICE INFORMATION

Predicate Device	**K102803** – Clarity™ Advanced Ceramic Brackets - 3M Unitek Corp **(Primary predicate)**

Indications for use:

Ceramic Brackets Orthometric are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Subject Device Description

The Orthometric's Ceramic Brackets are composed of different designs of brackets that are made of Aluminum Oxide. The ceramic brackets are ICERAM, ICERAM-P, and ICE CLEAR.

Substantial Equivalence

As is shown in the equivalence comparison between the subject device and predicate devices, they are equivalent in the product code, regulation number, and common name. The subject and predicate device have the same indications for use. All of them are indicated for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The subject device and the predicate K102803 have a color identification system indicating along the axis line a color ink dot. As well as the predicate, the subject device is delivered non-sterile to the end user and is intended to be used once by a single patient.

Like its predicate, the subject devices are manufactured from Aluminum Oxide (ceramic) material, which has a well-documented history of biocompatibility within the oral environment, meeting de requirement of ISO 10993. The subject device is equivalent to the predicate in Polycrystalline material composition.

The subject device and its predicate device incorporate equivalent torques, angulations, and slot sizes. Furthermore, the subject device and the K102803 have bases designed to provide maximum adhesion to the tooth while allowing easy and complete removal when necessary. Ceramic Brackets Orthometric and Clarity Advanced (K102803) have a ceramic bracket body with rounded contours and a low profile, twin design, providing more efficient movement mechanics with reduced friction.

As well as the Clarity Advanced, the subject device has different prescriptions, with and without hooks.

Performance tests were carried out to prove the technical equivalence between the Orthometric's Ceramic Brackets and the predicate Clarity Advanced Ceramic Brackets (K102803). The data demonstrates the similarity of the dimensional characteristics when compared. The results of adhesion strength tests demonstrate that both products had similar behavior, showing equivalence, both in the measurement of the external force necessary for detachment and in the shear stress. The Orthometric's Ceramic Brackets demonstrated similarity in the friction resistance test.

Table 5.1: Substantial equivalence comparison

Contents	Subject Device	Primary Predicate device	Equivalent Discussion
	Ceramic Brackets Orthometric	Clarity™ Advanced Ceramic Brackets – K102803	
	Orthometric Indústria e Comércio de Produtos Médicos e Odontológicos LTDA	3M Unitek Corp	
Product code	NJM	NJM	Equivalent
Common Name	Orthodontic Ceramic Brackets	Orthodontic Ceramic Brackets	Equivalent
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Equivalent
Indications for use	Ceramic Brackets Orthometric are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Clarity™ Advanced Cerâmicas Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Equivalent
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Equivalent
Single-use	YES	YES	Equivalent
Non-sterile	YES	YES	Equivalent
Material	Aluminum Oxide	Aluminum Oxide	Equivalent
Biocompatibility	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993	Equivalent

Maxillary Angulation	0 to 11	0 to 11	Equivalent
Maxillary Torque (°)	-22 to 18	-22 to 22	Equivalent
Slot Size	0.022''	0.022''	Equivalent
Bracket Design	Different prescriptions, with and without hooks;	Different prescriptions, with and without hooks;	Equivalent
Indication System	Colored-dot	Colored-dot	Equivalent

Non-Clinical Performance Data:

Ceramic Brackets Orthometric was tested following these standards:

- ISO 27020:2010 Dentistry – Brackets and tubes for use in Orthodontics;
- ISO 10993-1:2020 Biological evaluation of medical devices Evaluation and testing within a risk management process;
- ISO 10993-5:2009- Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10:2010 -Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ISO 10993-23:2021 – Biological evaluation of medical devices – Part 23: Tests for irritation;

Clinical performance Data:

No clinical data were included in this submission.

Conclusion:

The documentation submitted in this premarket notification demonstrates that the Ceramic Brackets have comparable features and performance and, therefore, are substantially equivalent to the predicate devices.