June 7, 2019

MEM Dental Technology Co., Ltd
Anita Chen
Official Correspondent
2F., No.22, Ln.31, Sec.1, Huandong Rd., Xinshi Dist.
Tainan City, 74146 Tw

Re: K180952
Trade/Device Name: Ceramic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: April 20, 2019
Received: May 6, 2019

Dear Anita Chen:

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,

Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180952

Device Name
Ceramic Bracket

Indications for Use *(Describe)*

Ceramic Bracket is indicated for orthodontic movement of natural 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) summary information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

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The assigned 510(k) Number: K180952

1. Submitter

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Date Prepared	2019.06.06

2 Device Name

Proprietary Name:	Ceramic Bracket
Common or Usual Name	Bracket, Ceramic, Orthodontic
Classification Name	Bracket Orthodontic Plastic Bracket (21 CFR 872.5470)
Product Code	NJM
Device	Ceramic Bracket
CFR Classification	CFR Part 872.5470
Device Class	II
Classification Panel	Dental

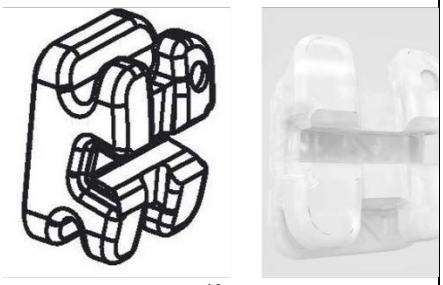
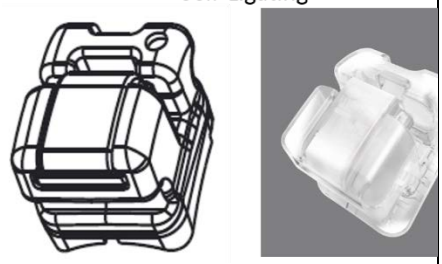
3 Primary Predicate

510(k) number	K160615

	Device name	Orthodontic Ceramic Brackets 1.1
	Manufacturer	TOMY, INC 6 tenko blg. 3-16-7 midoricho, fuchu city, JP 183-0006
4	Device Description	Ceramic bracket are designed to move teeth to improve their alignment. Ceramic bracket are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position. Ceramic bracket are intended for use in affixed to a tooth so that pressure can be exerted on the teeth. Use bonding supplies to bond the bracket on to a tooth. Use bonding supplies to bond the bracket on to a tooth. Ceramic bracket are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.
5.	Indication for Use:	Ceramic bracket is indicated for orthodontic movement of natural teeth.
6.	Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the Ceramic bracket is substantially equivalent to the predicate device as summarized in *Table 1*.

Table 1

Manufacturer	MEM Dental Technology Co., Ltd.	Tomy, Inc.
Device name	Subject Device Ceramic bracket	Primary Predicate Device Orthodontic Ceramic Brackets 1.1
510(k) Number	K180952	K160615
Indication for Use	Ceramic bracket is indicated for orthodontic movement of natural teeth.	Orthodontic Ceramic Brackets 1.1 are indicated for orthodontic movement of natural teeth.
Classification name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Rag Number	872.5470	872.5470
Product Code	NJM	NJM
Class	II	II
Medical Specialty	Dental	Dental
Ligation	Non-Self-Ligating Self-Ligating	Non-Self-Ligating Self-Ligating
Base	Mechanical Lock Base	Mechanical Lock Base
Sterility	Non-Sterile	Non-Sterile
Materials	Polycrystalline (translucent) alumina	Polycrystalline (translucent) alumina
Utility	Single-use only	Single-use only
Design	Archwire slot, tiewings for ligature and identification marks for placement Hooks for ligation, for additional tooth movement Molded ceramic body with rounded corners and e Slot to hold orthodontic wires edges	Archwire slot, tiewings for ligature and identification marks for placement Hooks for ligation, for additional tooth movement Molded ceramic body with rounded corners and e Slot to hold orthodontic wires edges

Manufacturer	MEM Dental Technology Co., Ltd.	Tomy, Inc.
Device name	Subject Device Ceramic bracket	Primary Predicate Device Orthodontic Ceramic Brackets 1.1
510(k) Number	K180952	K160615
Picture of Device	Non-Self-Ligating  Self-Ligating 	Non-Self-Ligating Mandibular Bicuspid  Non-Self-Ligating for all other Teeth  Self-Ligating Mandibular Bicuspid  Self-Ligating for all other Teeth 

7. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the device:

• ISO 27020 First edition 2010-12-15 Dentistry - Brackets and Tubes for use in Orthodontics

Ceramic Bracket.

All of the components found in the Ceramic Bracket have been used in legally marketed devices, such as the primary predicate Orthodontic Ceramic Brackets 1.1.

Biocompatibility Testing

The biocompatibility evaluation and testing of the Product name was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Draft Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing", dated 04-23-2013
- ISO 10993-3,Biological evaluation of medical device-Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO 10993-5, Biological evaluation of medical device-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10, Biological evaluation of medical device-Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11, Biological evaluation of medical device-Part 11: Tests for systemic toxicity.
- ISO 10993-12, Biological evaluation of medical device-Part 12: Sample preparation and reference materials.

Sterilization Status

The Ceramic Bracket are provided non-sterile and are not processed prior to use.

Mechanical testing

Ceramic bracket's mechanical function including Shear Bond Strength, Torque Strength test and structure integrity were tested. The results were compared to recognized standards (ISO 6872:2015, ISO 29022:2013, ISO 27020:2010, ISO 6474-2:2012) and clinical literature data to demonstrate substantial equivalence.

No animal studies or clinical testing have been required for these devices.

8. Conclusion

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Ceramic bracket is substantially equivalent.