DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 26, 2016

Tomy, Inc.
c/o Ms. Carolyn Primus
Consultant
Primus Consulting
7046 Owls Nest Terr
Bradenton, Florida 34203

Re: K160615
Trade/Device Name: Orthodontic Ceramic Brackets 1.1
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: July 24, 2016
Received: July 28, 2016

Dear Ms. Carolyn Primus:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K16 0615

Device Name
ORTHODONTIC CERAMIC BRACKETS 1.1

Indications for Use *(Describe)*
ORTHODONTIC CERAMIC BRACKETS 1.1 are 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.

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510(k) Summary
per 21CFR807.92

I. SUBMITTER

TOMY, Inc.
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183-0006
Japan

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Contact Person: Mr. Jinichi Watanabe Date
Prepared: August 24, 2016

II. DEVICE

Name of Device: ORTHODONTIC CERAMIC BRACKETS 1.1
Common or Usual Name: Bracket, Ceramic, Orthodontic
Classification Name: Orthodontic plastic bracket (21 CFR 872.5470)
Regulatory Class: II
Product Code: NJM

III. PREDICATE DEVICES

ORTHODONTIC CERAMIC BRACKETS are substantially equivalent to the following predicate devices with respect to intended use, materials, and design:

510(k) #	Device	Manufacturer
K102803 (primary)	Clarity Advanced Ceramic Brackets	3M Unitek Corp.
K123094 (secondary)	Orthodontic Ceramic Brackets	TOMY, Inc.

ORTHODONTIC CERAMIC BRACKETS 1.1 are equivalent to Clarity Advanced Ceramic Brackets (K102803) with regard to indications for use, materials, technological characteristics, and device design. ORTHODONTIC CERAMIC BRACKETS 1.1 have been slightly modified from TOMY Orthodontic Ceramic Brackets (K123094) to allow for the inclusion of the use of brackets for the mandibular bicuspid.

IV. DEVICE DESCRIPTION:

ORTHODONTIC CERAMIC BRACKETS 1.1 are designed to move teeth to improve their alignment.

ORTHODONTIC CERAMIC BRACKETS 1.1 are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.

V. INDICATIONS FOR USE:

ORTHODONTIC CERAMIC BRACKETS 1.1 are indicated for orthodontic movement of natural teeth.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

ORTHODONTIC CERAMIC BRACKETS 1.1 are composed of a polycrystalline alumina ceramic, and have an orthodontic bracket design, which includes an archwire slot and tiewings. The self-ligating ORTHODONTIC CERAMIC BRACKETS 1.1 have a metal clip so that no other ligation of the archwire is needed.

Bench testing was performed to ensure that the ORTHODONTIC CERAMIC BRACKETS 1.1 performance was achieved and verified.

The ORTHODONTIC CERAMIC BRACKETS 1.1 were not evaluated for biocompatibility because the materials are the same as the legally marketed predicates. TOMY made no material changes or manufacturing process changes since the clearance of their already marketed Orthodontic Ceramic Brackets (K123094). Therefore, no new questions of substantial equivalence are raised with the subject devices.

We believe the ORTHODONTIC CERAMIC BRACKETS 1.1 are substantially equivalent to the predicate devices identified above. The difference between the ORTHODONTIC CERAMIC BRACKETS 1.1 and the Orthodontic Ceramic Brackets (K123094) that TOMY currently markets is the INCLUSION of the brackets for the mandibular bicuspid. Additionally, the ORTHODONTIC CERAMIC BRACKETS 1.1 have the same intended use, composition, design, function, physical properties, and performance of the predicate device, 3M Unitek Corp.'s Clarity Advanced Ceramic Brackets (K102803). However, the difference being that the ORTHODONTIC CERAMIC BRACKETS 1.1 includes both self-ligating and non-self-ligating, whereas Clarity Advanced are non-self-ligating. However, self-ligating brackets would not be expected to impact the intended use

or performance of the brackets on the mandibular bicuspids.

We believe that the performance data provided herein support the substantial equivalence of the ORTHODONTIC CERAMIC BRACKETS 1.1.

Table VI-1 below provides a comparison of the subject devices and the predicate devices.

Table VI-1. Comparison of Subject ORTHODONTIC CERAMIC BRACKETS 1.1 to Predicates (3M Unitek Clarity Advanced Ceramic Brackets, K102803 and TOMY Orthodontic Ceramic Brackets, K123094)

	Subject Device **ORTHODONTIC CERAMIC BRACKETS 1.1**	**Primary Predicate Device** **Clarity Advanced Ceramic Brackets**	**Secondary Predicate Device** **Orthodontic Ceramic Brackets**
510(k) Number	N/A	K102803	K123094
Manufacture	TOMY Inc.	3M Unitek Corp.	TOMY Inc.
Device Name	Bracket, Ceramic, Orthodontic	Bracket, Ceramic, Orthodontic	Bracket, Ceramic, Orthodontic
Description	Orthodontic ceramic bracket	Orthodontic ceramic bracket	Orthodontic ceramic bracket
Medical Specialty	Dental	Dental	Dental
Product Code	NJM	NJM	NJM
Rag Number	872.5470	872.5470	872.5470
Class	2	2	2
Materials	Polycrystalline (translucent) alumina	Polycrystalline (translucent) alumina	Polycrystalline (translucent) alumina
Base	Mechanical Lock Base	Glass-grit roughened Base	Mechanical Lock Base
Design	Archwire slot, tiewings for ligature and identification marks for placement	Archwire slot, tiewings for ligature and identification marks for placement	Archwire slot, tiewings for ligature and identification marks for placement
	Hooks for ligation, for additional tooth movement	Hooks for ligation, for additional tooth movement	Hooks for ligation, for additional tooth movement
	Molded ceramic body with rounded corners and edges	Molded ceramic body with rounded corners and edges	Molded ceramic body with rounded corners and edges
	Slot to hold orthodontic wires	Slot to hold orthodontic wires	Slot to hold orthodontic wires
Ligation	Non-Self-Ligating Self-Ligating	Non-Self-Ligating	Non-Self-Ligating Self-Ligating
Indications for Use	ORTHODONTIC CERAMIC BRACKETS 1.1 are indicated for orthodontic movement of natural teeth.	Clarity Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Orthodontic Ceramic Brackets are indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.
Sterility	Non-Sterile	Non-Sterile	Non-Sterile
Utility	Single-use Only	Single-use Only	Single-use Only

	Subject Device **ORTHODONTIC CERAMIC BRACKETS 1.1**	**Primary Predicate Device** **Clarity Advanced Ceramic Brackets**	**Secondary Predicate Device** **Orthodontic Ceramic Brackets**
Picture of Device	Non-Self-Ligating Mandibular Bicuspid  Non-Self-Ligating for all other Teeth  Self-Ligating Mandibular Bicuspid  Self-Ligating for all other Teeth 	Non-Self-Ligating 	Non-Self-Ligating  Self-Ligating 

VII. PERFORMANCE DATA

ORTHODONTIC CERAMIC BRACKETS 1.1 conform to the following Recognized Consensus Standard:

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

ORTHODONTIC CERAMIC BRACKETS 1.1 were tested for Shear Bond Strength and Torque Strength.

All of the components found in the ORTHODONTIC CERAMIC BRACKETS 1.1 have been used in legally marketed devices. ORTHODONTIC CERAMIC BRACKETS 1.1 have the same composition as the predicate devices. Therefore, further biocompatibility testing is not necessary.

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

VIII. CONCLUSIONS

There are no known substantial differences in terms of composition and mechanical properties between the ORTHODONTIC CERAMIC BRACKETS 1.1 and the predicate devices. This new 510(k) includes Orthodontic Ceramic Brackets (K123094) and their modified brackets. The difference in the modified brackets is the addition of the mandibular bicuspid brackets. Thus, the indication of use is equivalent to the predicate device Clarity ADVANCED Ceramic Brackets (K102803).. The technological characteristics and materials are identical to Orthodontic Ceramic Brackets (K123094). Therefore, we believe that the information provided herein demonstrates that the ORTHODONTIC CERAMIC BRACKETS 1.1 are substantially equivalent to the predicate devices in design, principles of performance, and intended use.