TOMY, Inc.
% Ruthanne Vendy
Principal Specialist
Regulatory & Quality Solutions, Inc.
2790 Mosside Blvd. #800
Monroeville, Pennsylvania 15146

October 30, 2018

Re: K180718
Trade/Device Name: Orthodontic Plastic Bracket and Accessories
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: DYW
Dated: August 22, 2018
Received: August 29, 2018

Dear Ruthanne Vendy:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180718

Device Name
ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES

Indications for Use *(Describe)*
ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES 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.

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

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510(k) Summary
K180718

Date Prepared: October 25, 2018

I. SUBMITTER

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Japan

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II. DEVICE

Primary Classification:
Name of Device: ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES
Common or Usual Name: Bracket, Plastic, Orthodontic
Classification Name: Orthodontic plastic bracket (21 CFR 872.5470)
Regulatory Class: II
Product Code: DYW

III. PREDICATE AND REFERENCE DEVICES

DENTSPLY Elation MB Metal Reinforced Plastic Brackets, K092030 (Primary Predicate)
CDB Corporation CDB Clip, K080906
GESTENCO INTERNATIONAL AB Orthodontic Polymer Composite Bracket, K053055
DENTSPLY NEO-CLIP Orthodontic Bracket Accessory, K042905

IV. DEVICE DESCRIPTION

The ORTHODONTIC PLASTIC BRACKETS are designed to move teeth to improve their alignment. The ORTHODONTIC PLASTIC BRACKETS are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position. Some variations can be used with bracket caps. The ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES consist of plastic orthodontic brackets, bracket caps, and buttons. The bracket caps are designed as an accessory of the orthodontic brackets for holding the archwire in the bracket's slot. Bracket caps are placed on the labial/buccal side of the brackets. The plastic buttons are designed to move teeth to improve their alignment. The plastic buttons are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position. The button design includes a round slot for attaching wires or other appliances.

V. INDICATIONS FOR USE: ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are indicated for orthodontic movement of natural teeth.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The below tables (**Tables VI-1, VI-2 and VI-3**) provide a comparison of the subject devices and the predicate devices. Table VI-1 is a comparison of the brackets; Table VI-2 is a comparison of the bracket caps; and Table VI-3 is a comparison of the bracket buttons.

Table VI-1 Comparison of DENTSPLY ELATION MB Metal Reinforced Plastic Bracket (K092030) to Subject ORTHODONTIC PLASTIC BRACKETS

	ORTHODONTIC PLASTIC BRACKETS (Subject)	DENTSPLY ELATION MB Metal Reinforced Plastic Bracket (K092030)	Equivalence Analysis
Indications for Use	ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are indicated for orthodontic movement of natural teeth.	Elation MB is indicated for orthodontic movement of natural teeth.	Substantially Equivalent
Device Name Description Medical Specialty Product Code Reg Number Class	Device: Bracket, Plastic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position. Regulation Medical Specialty: Dental Review Panel: Dental Product Code: DYW Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Device: Bracket, Plastic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position. Regulation Medical Specialty: Dental Review Panel: Dental Product Code: DYW Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Substantially Equivalent
Patient Contact Materials	Made of Polycarbonate, Polyethylene terephthalate, Polybutylene terephthalate, and Stainless Steel AISI 304	Made of Polycarbonate, Polyethylene terephthalate, Polybutylene terephthalate, and Stainless Steel AISI 304	Substantially Equivalent
Sterility	Non-Sterile	Non-Sterile	Substantially Equivalent
Sterilization	Not to be sterilized	Not to be sterilized	Substantially Equivalent
Utility	Single Use Only	Single Use Only	Substantially Equivalent
Energy Source	Manually operated—Non-electrical	Manually operated—Non-electrical	Substantially Equivalent
Visual Identification for tooth placement	A color dot is applied to the distogingival tie-wing for visual identification. Color Codes: UR & UL CENTRALS: BLUE UR & UL LATERALS: PINK UR & UL CUSPIDS: GREEN UR & UL BICUSPIDS: VIOLET LOWER ANTERIORS: ORANGE LR & LL CUSPIDS: LIGHT BLUE LR & LL 1st BICUSPIDS: GREY LR & LL 2nd BICUSPIDS: BLACK	A color dot is applied to the distogingival tie-wing for visual identification. Color Codes: U1 Blue U2 Pink U3 Green U4-5 Violet L1-2 Orange L3 Light Blue L4 Grey L5 Black	Substantially Equivalent
Application to teeth	Bonded	Bonded	Substantially Equivalent
Manufacturing Method	Injection Molded	Injection Molded	Substantially Equivalent
Mechanical Lock Base	Yes	Yes	Substantially Equivalent

	ORTHODONTIC PLASTIC BRACKETS (Subject)	DENTSPLY ELATION MB Metal Reinforced Plastic Bracket (K092030)	Equivalence Analysis
Metal Reinforced	Yes	Yes	Substantially Equivalent
Picture of Device (BRACKET)			

Table VI-2 Comparison of CDB CORPORATION CDB CLIP (K080906) to Subject ORTHODONTIC PLASTIC BRACKET CAPS

	ORTHODONTIC PLASTIC BRACKET CAPS (Subject)	CDB CORPORATION CDB CLIP (K080906)[1]	Equivalence Analysis
Indications for Use	ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are indicated for orthodontic movement of natural teeth.	The CDB Clip, commonly known as an orthodontic ligating clip, is an orthodontic bracket accessory. It attaches to the orthodontic bracket to hold the archwire firmly in the slot Together they facilitate the orthodontic movement of teeth.	Substantially Equivalent
Device Name Description Medical Specialty Product Code Reg Number Class	Device: Bracket, Plastic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position. Regulation Medical Specialty: Dental Review Panel: Dental Product Code: DYW Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Device: Bracket, Ceramic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic ceramic bracket is a device composed of ceramic, which is intended to be bonded to a tooth, upon which an orthodontic wire is used to move the tooth to a new postion. (the current classification only specifies plastic brackets. Confusion exists as to whether ceramic brackets are regulated.) Regulation Medical Specialty: Dental Review Panel: Dental Product Code: NJM Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Product Codes are different, however the devices are under the same regulation
Patient Contact Materials	Polyoxymethylene acetyl polymer	Polyoxymethylene acetyl polymer	Substantially Equivalent
Sterility	Non-Sterile	Non-Sterile	Substantially Equivalent
Sterilization	Not to be sterilized	Not to be sterilized	Substantially Equivalent
Utility	Single Use Only	Single Use Only	Substantially Equivalent
Energy Source	Manually operated—Non-electrical	Manually operated—Non-electrical	Substantially Equivalent
Manufacturing Method	Injection Molded	Injection Molded	Substantially Equivalent
Picture of Device (CAP)		Image Unavailable	

[1] K080906 CDB Clip is identical to the Dentsply International K042905 NEO-CLIP ORTHODONTIC BRACKET ACCESSORY. There is no difference in the fundamental technology. The CDB Clip is made of the same material and has the same overall intended use.

Table VI-3 Comparison of GESTENCO INTERNATIONAL AB ORTHODONTIC POLYMER COMPOSITE BRACKET (K053055) to Subject ORTHODONTIC PLASTIC BRACKET BUTTONS

	ORTHODONTIC PLASTIC BUTTONS (Subject)	**DENTSPLY ELATION MB Metal Reinforced Plastic Bracket (K092030)**	**GESTENCO INTERNATIONAL AB ORTHODONTIC POLYMER COMPOSITE BRACKET (K053055)**	**Equivalence Analysis**
Indications for Use	ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are indicated for orthodontic movement of natural teeth.	Elation MB is indicated for orthodontic movement of natural teeth.	Orthodontic Polymer Composite Bracket is intended to be bonded on teeth to aid in the movement of patient's teeth during orthodontic treatment.	Substantially Equivalent
Device Name Description Medical Specialty Product Code Reg Number Class	Device: Bracket, Plastic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position. Regulation Medical Specialty: Dental Review Panel: Dental Product Code: DYW Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Device: Bracket, Plastic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position. Regulation Medical Specialty: Dental Review Panel: Dental Product Code: DYW Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Device: Bracket, Plastic, Orthodontic Regulation Description: Orthodontic plastic bracket Definition: An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position. Regulation Medical Specialty: Dental Review Panel: Dental Product Code: DYW Submission Type: 510(k) Regulation Number: 872.5470 Device Class: 2	Substantially Equivalent
Patient Contact Materials	Polycarbonate, Polyethylene terephthalate, Polybutylene terephthalate	Made of Polycarbonate, Polyethylene terephthalate, Polybutylene terephthalate, and Stainless Steel AISI 304	Polycarbonate	Substantially Equivalent to K092030
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Substantially Equivalent
Sterilization	Not to be sterilized	Not to be sterilized	Not to be sterilized	Substantially Equivalent
Utility	Single Use Only	Single Use Only	Single Use Only	Substantially Equivalent
Energy Source	Manually operated—Non-electrical	Manually operated—Non-electrical	Manually operated—Non-electrical	Substantially Equivalent
Manufacturing Method	Injection Molded	Injection Molded	Injection Molded	Substantially Equivalent
Picture of Device				

VII. PERFORMANCE DATA

ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES conform to the following Recognized Consensus

Standards:

- ISO 27020 First edition 2010-12-15 “Dentistry - Brackets and Tubes for use in Orthodontics”
- ISO 7405: 2008 “Dentistry — Evaluation of biocompatibility of medical devices used in dentistry”
- ISO 10993-1:2009 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”

Additionally, the ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES were successfully tested for Tensile Strength, Elongation, and Shear Bond Strength. The tensile and elongation tests were performed to determine no significant deterioration with aging. New and aged brackets exceeded the criteria of ≥50 MPa for tensile strength and ≥ 100% elongation. The average shear bond strengths were greater than 100 N for wet and dry conditions, which exceeded the internal test criteria for shear bond strength.

All the components and manufacturing processes found in the ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are identical to the materials used in legally marketed devices (DENTSPLY ELATION MB Metal Reinforced Plastic Bracket [K092030] and DENTSPLY NEO-CLIP ORTHODONTIC BRACKET ACCESSORY [K042905]) and/or were found acceptable for dental use. ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are the same and/or of the equivalent composition as the predicate devices. Therefore, further biocompatibility testing is not necessary.

No animal studies or clinical testing were required for these devices.

VIII. CONCLUSIONS

There are no substantial differences in terms of composition and mechanical properties between the ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES and the predicate devices. The indications for use are comparable and any differences in technological characteristics do not raise any new questions of substantial equivalence. Therefore, we believe that the information provided herein demonstrates that the ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are substantially equivalent to the predicate and reference devices in design, principle of performance, and intended use.