DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 3, 2017

Dentsply Sirona
Ms. Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60
York, Pennsylvania 17408

Re: K163155
Trade/Device Name: MTM Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 9, 2016
Received: November 10, 2016

Dear Helen Lewis:

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,

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)*

K163155

Device Name

MTM® Clear Aligner

Indications for Use *(Describe)*

MTM® Clear Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements, MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.

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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Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

510(k) SUMMARY
for
MTM® Clear Aligner
(K163155)

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 19 January 2017

2. Device Name:

- Proprietary Name: MTM® Clear Aligner
- Classification Name: Aligner, Sequential
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC

3. Predicate Devices:

Predicate Device Name	510(k)	Company Name
MTM® Clear Aligner	K132145	Raintree Essix Inc.
ClearPath Aligner	K123514	ClearPath Orthodontics

4. Description of Device:

MTM® Clear Aligner consists of a series of custom made removable plastic orthodontic appliances that sequentially positions teeth by way of continuous gentle force.

5. Indications for Use:

MTM® Clear Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements, MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.

Indications for Use Comparison:

In this submission we focus on removing mention of specific movement types from the indications for use statement of the primary predicate. The indications for use are similar between the primary predicate MTM® Clear Aligner and the proposed MTM® Clear Aligner with expanded indications. Both devices are indicated for the correction of anterior tooth misalignments (malocclusions) in

patients with permanent teeth, using a series of aligners. The primary predicate specifies that four types of tooth movement are used, whereas the proposed MTM® Clear Aligner removes the specific tooth movement types from the indications for use statement, to allow all types of tooth movement to be used.

The indications for use are fundamentally the same between the reference predicate, ClearPath Aligner and the proposed MTM® Clear Aligner. Both devices are indicated for the correction of anterior tooth misalignments (malocclusions) in patients with permanent teeth, using a series of aligners. Neither of them specify the types of tooth movement to be used.

The change in the indications for use to remove specific tooth movement types for the proposed MTM® Clear Aligner does not result in a new intended use for the current, primary predicate MTM® Clear Aligner. This change does not raise new concerns as evidenced in the scientific literature reviewed.

6. Substantial Equivalence:

Table 5.1 Device Comparison Table

Element	Proposed Device	Primary Predicate	Reference Predicate	Comparison
510(k)	K163155	K132145	K123514	N/A
Device Name	MTM® Clear Aligner	MTM® Clear Aligner	ClearPath Aligner	N/A
Manufacturer	Raintree Essix Inc.	Raintree Essix Inc.	ClearPath Orthodontics	N/A
Intended Use	Treatment of anterior tooth malocclusions in patients with permanent dentition	Treatment of anterior tooth malocclusions in patients with permanent dentition	Correction of dental malocclusion in patients with permanent dentition	Same
Indications for Use	MTM® Clear Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements, MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.	MTM® Clear Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements (torque, tipping, rotation and bodily movement), MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.	The ClearPath Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The ClearPath Aligner is intended for minor anterior tooth movement by way of continuous gentle force.	Same as reference predicate. Removing specific movement types from primary predicate IFU statement.
Tooth Movement Types	All	All except intrusion and extrusion.	All	Same as reference predicate. Removing specific movement types from primary predicate IFU statement to allow for intrusive and extrusive movements.
Material	Co-polyester or Co-polymer	Co-polyester or Co-polymer	Co-Polyester	Same
Mode of Action	Continuous gentle force applied to teeth to achieve movement.	Continuous gentle force applied to teeth to achieve movement.	Continuous gentle force applied to teeth to achieve movement.	Same
Features	Sequential thermoformed plastic aligners used in the alignment of teeth by application of continuous gentle force. Aligners can be removed by the patient for eating and cleaning. Aligners are most effective when worn 20-22 hours per day.	Sequential thermoformed plastic aligners used in the alignment of teeth by application of continuous gentle force. Aligners can be removed by the patient for eating and cleaning. Aligners are most effective when worn 20-22 hours per day.	Sequential thermoformed plastic aligners used in the alignment of teeth by application of continuous gentle force. Aligners can be removed by the patient for eating and cleaning. Aligners are most effective when worn 20-22 hours per day.	Same

The technological characteristics of the proposed MTM® Clear Aligner are unchanged from those of the primary predicate MTM® Clear Aligner device cleared under premarket notification K132145.

7. Non-Clinical Performance Data

No additional non-clinical bench testing has been included in this submission. Non-clinical data was previously submitted and reviewed to support clearance of the primary predicate MTM® Clear Aligner under premarket notification K132145.

8. Clinical Performance Data

No new human clinical data has been included in this submission; however a literature review was conducted. Clinical data was previously submitted and reviewed to support clearance of the primary predicate MTM® Clear Aligner under premarket notification K132145, as well as in a prior submission for the MTM® Clear Aligner In-Office system under premarket notification K123925. This data demonstrated performance of the predicate MTM® Clear Aligner for sequential minor incremental tooth movements using Raintree Essix plastics with force point technology. A literature review was conducted in support of the proposed device modification. The literature review is included in this submission to provide valid scientific evidence for intrusive and extrusive orthodontic tooth movements achieved with clear aligner therapy.

9. Conclusion Regarding Substantial Equivalence

The data submitted for non-clinical and clinical performance testing, as well as the technological characteristics of the proposed MTM® Clear Aligner device support substantial equivalence when compared to the predicate devices.