October 18, 2023

Dentsply Sirona Inc.
Sobrin Laura
Corporate RA Manager
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K230199
Trade/Device Name: Byte Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 25, 2023
Received: January 25, 2023

Dear Sobrin Laura:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, 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)*
K230199

Device Name

Byte Aligner System

Indications for Use *(Describe)*

The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System 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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510(k) SUMMARY
For Byte Aligner System (K230199)

1. Submitter Information:

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

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Fax number: 717-849-4343

Date Prepared: October 13, 2023

2. Device Name:

- Proprietary Name: Byte Aligner System
- Classification Name: Orthodontic plastic bracket
- CFR Number: 21 CFR 872.5470
- Device Class: Class II
- Product Code: NXC, Aligner, Sequential

3. Predicate & Reference Devices:

Device Name	Device Type	510(k)	Company Name
Byte Aligner System	Predicate	K180346	Straight Smile, LLC (part of Dentsply Sirona)
Sureclear Aligners	Reference	K171860	OraMetrix (part of Dentsply Sirona), now Dentsply Sirona Orthodontics Inc.
Mouthguard and Aligner Materials	Reference	K062828	Dentsply International (part of Dentsply Sirona), now Dentsply Sirona Orthodontics Inc.
Invisalign System with Mandibular Advancement Feature	Reference	K181739	Align Technology Inc.

Device Name	Device Type	510(k)	Company Name
Ormco Spark Aligner System	Reference	K182826	Sybron Dental Specialties

4. Description of Device:

The Byte Aligner System consists of a sequential series of aligners fabricated of clear, thin, lightweight and flexible thermoformed polyethylene terephthalate glycol (PETG) [copolyester] plastics.

The mechanism of action of the proposed Byte Aligner System is mechanical in nature; that is, tooth movement induced by orthodontic force application using continuous gentle forces. The aligners are made from elastic thermoplastic material that applies continuous gentle force to the teeth for treatment of tooth malocclusion. Treatment plans are modeled using CAD-CAM (computer-aided-design and computer-aided-manufacturing) software. Model archforms are created using rapid prototyping techniques like stereo-lithography. The aligners are thermoformed over the model archforms and are not themselves 3D printed.

With the aligners seated on the patient's upper and/or lower dental arches, the teeth are progressively and gradually straightened over time by mechanical forces that are delivered via minor, incremental changes in tooth positions in each subsequent set of aligner trays that have been customized for the patient, delivered as a sequential series of trays to progressively reposition the teeth. The mechanics of how this happens is based on the forces caused by the elastic deformation of the aligner when worn by the patient. The forces are applied to the teeth, and also to the roots, causing pressure to the periodontium in the direction of the desired movement. Each aligner moves the patient's teeth in small increments from their original state.

5. Indications for Use:

The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System positions teeth by way of continuous gentle force.

6. Comparison of Technological Characteristics:

The purpose of this Traditional 510(k) is to gain U.S. premarket clearance for the modification to the predicate device Byte Aligner System (K180346).

- The proposed and predicate device have the same intended use, patient population and indications for use.
- The proposed and predicate devices are made by thermoforming PETG (copolyester) plastic sheets.
- The proposed and predicate devices have the same packaging configurations.

The key differences between the predicate device (K180346) and the proposed device are:

- The proposed device can be made by thermoforming additionally cleared PETG (copolyester) plastic sheets (K062828), and which follows the same manufacturing processes and materials as reference device Sureclear Aligners (K171860).
- Reference to two additional cleared orthodontic software systems (K213916, K171860) that can be used for treatment planning software prior to the fabrication of the proposed device.
- Revise product label to only include date of manufacture and exclude an expiration date to be consistent with the reference device Sureclear Aligners (K171860).
- Separate Instructions for Use for patient and doctor. Update patient Instructions for Use to be more aligned with requirements in FDA guidance document, "Guidance on Medical Device Patient Labeling". Create separate Instructions for Use geared towards the dentist.
- Allow for the use of cut-outs, slits and attachments similar to the reference devices (K181739 and K182826).

An overview of the similarities and differences between the proposed devices, predicate device, and reference devices is given in Table FS.1.

Table FS.1: Similarities and Differences between the Proposed device, Predicate device, and Reference devices

Item of Comparison	Proposed device Byte Aligner System (K230199)	Predicate device Byte Aligner System (K180346)	Reference device Sureclear Aligners (K171860)	Reference device Essix plastic sheets (K062828)	Reference device Invisalign System with Mandibular Advancement Feature (K181739)	Reference device Ormco Spark Aligner System (K182826)	Discussion
Manufacturer	Straight Smile, LLC (part of Dentsply Sirona)	Straight Smile, LLC (part of Dentsply Sirona)	OraMetrix (part of Dentsply Sirona), now Dentsply Sirona Orthodontics Inc.	Dentsply International (part of Dentsply Sirona), now Dentsply Sirona Orthodontics Inc.	Align Technology, Inc.	Sybron Dental Specialties	The proposed and predicate devices are Dentsply Sirona devices. Some reference devices are Dentsply Sirona devices or third-party devices.
Intended population	Patients with permanent dentition	Patients with permanent dentition	Patients with permanent dentition		Patients with permanent dentition	Patients with permanent dentition	Same
Indications for Use	The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System positions teeth by way of continuous gentle force.	The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System positions teeth by way of continuous gentle force.	Sureclear aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition.	Mouthguard and Aligner Materials are indicated for the fabrication of orthodontic and dental appliances such as aligners, bite planes, mouthguards, nightguards, snoring appliances, splints, retainers, repositioners, and temporary bridges.	The Invisalign System is indicated for the orthodontic treatment of malocclusion.	The Ormco™ Spark™ Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e., all second molars). The Ormco™ Spark™ Aligner System positions teeth by way of continuous gentle force.	Same as the predicate device. Similar to the reference devices.

Item of Comparison	Proposed device Byte Aligner System (K230199)	Predicate device Byte Aligner System (K180346)	Reference device Sureclear Aligners (K171860)	Reference device Essix plastic sheets (K062828)	Reference device Invisalign System with Mandibular Advancement Feature (K181739)	Reference device Ormco Spark Aligner System (K182826)	Discussion
Mechanism of action	Sequential aligners are made from elastic thermoplastic materials that apply continuous gentle force to the teeth in the form of stored energy imparted in the aligner trays at the time of their fabrication. This energy slowly dissipates over time, and re-positions the teeth by way of continuous gentle force.	Sequential aligners are made from elastic thermoplastic materials that apply continuous gentle force to the teeth in the form of stored energy imparted in the aligner trays at the time of their fabrication. This energy slowly dissipates over time, and re-positions the teeth by way of continuous gentle force.	Sequential aligners are made from elastic thermoplastic materials that apply continuous gentle force to the teeth in the form of stored energy imparted in the aligner trays at the time of their fabrication. This energy slowly dissipates over time, and re-positions the teeth by way of continuous gentle force.		Sequential aligners apply continuous gentle force to the teeth and position the mandible forward	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental clinician's prescription.	Same as the predicate device and reference device Sureclear Aligners (K171860). Similar to the reference devices.
Aligner Tray Raw material used	PETG (copolyester)	PETG (copolyester)	PETG (copolyester)	Various thermoplastic sheets including PETG (copolyester) plastic sheets	Polyurethane-polyester composite resin	Polyurethane-polyester composite resin	Similar. Proposed device uses the same plastic sheet materials in the predicate device and reference device Sureclear Aligners (K171860).
Manufacturing process	Thermoforming plastic sheets over 3D printed model	Thermoforming plastic sheets over 3D printed model	Thermoforming plastic sheets over 3D printed model	Thermoforming plastic sheets over 3D printed model	Thermoforming plastic sheets over 3D printed model	Thermoforming plastic sheets over 3D printed model	Same

Item of Comparison	Proposed device Byte Aligner System (K230199)	Predicate device Byte Aligner System (K180346)	Reference device Sureclear Aligners (K171860)	Reference device Essix plastic sheets (K062828)	Reference device Invisalign System with Mandibular Advancement Feature (K181739)	Reference device Ormco Spark Aligner System (K182826)	Discussion
Tooth movements	Tooth movements available include the full range necessary to provide full orthodontic treatment of patients with permanent dentition, consistent with the Indications for Use.	Tooth movements available include the full range necessary to provide full orthodontic treatment of patients with permanent dentition, consistent with the Indications for Use.	Tooth movements available include the full range necessary to provide full orthodontic treatment of patients with permanent dentition, consistent with the Indications for Use.		Tooth movements consistent with the Indications for Use, including mandibular advancement.	Tooth movements consistent with the Indications for Use.	Same as the predicate and reference device, Sureclear aligners (K171860) Similar to other reference devices (K181739 & K182826)
Sterility state	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Single Patient use	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use	Same
Shelf Life	No shelf life	2 years	No shelf life	No shelf life	No shelf life	No shelf life	Same as the reference devices
OTC or Rx	Rx	Rx	Rx	Rx	Rx	Rx	Same
Attachments	Available	Available	Available		Available	Available	Same
Cut-outs/Slits	Available				Available	Available	Same as the reference devices (K181739, K182826)

Item of Comparison	Proposed device Byte Aligner System (K230199)	Predicate device Byte Aligner System (K180346)	Reference device Sureclear Aligners (K171860)	Reference device Essix plastic sheets (K062828)	Reference device Invisalign System with Mandibular Advancement Feature (K181739)	Reference device Ormco Spark Aligner System (K182826)	Discussion
In use duration	Aligners are worn for 7-14 days (1-2 weeks) or as directed by the dentist. Aligners are to be worn 20-22 hours (24/7) except when eating, drinking, brushing or flossing.	Each month, wear the first set for 1 week, the second set for 1 week, and the third set for 2 weeks.	Aligners should be worn 20 to 22 hours daily. Each set of aligners should be replaced after approximately 2 weeks of use.		Aligners are worn for approximately 1-2 weeks of 20-22 hours of wear per day. This is repeated for duration as prescribed by the dental practitioner.	Aligners are worn every one or two weeks as part of the personalized treatment plan.	Similar Aligners are worn for 7-14 days (1-2 weeks) for the proposed device and ranges between 1 to 2 weeks for the predicate and reference devices. The proposed labeling standardizes the wear time for the end user regardless of aligner stage and makes it easier for the patient to adhere to their tray change regimen.
Software used for ordering workflow	Yes	Yes	Yes				Same

7. Non-Clinical Performance Data

Testing data that was referenced, or data relied upon to demonstrate substantial equivalence include:

a) Biocompatibility evaluation in accordance with EN ISO 10993-1:2018 (Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process) was performed and it was determined that no additional testing was required to demonstrate biological safety of proposed devices. Testing on file in Sureclear Aligners (K171860) remains valid.

b) Shelf-life information included in Mouthguard and Aligner Materials (K062828) and Sureclear Aligners (K171860) was reviewed, in addition to literature, and considered to be sufficient evidence to support the addition of alternate PETG (copolyester) materials and modification to the finished device shelf-life.

c) Literature and material data sheet review was performed on the predicate device (K180346) PETG polyester materials and the proposed PETG polyester materials and confirmed that the materials are very similar in characteristics and performance.

8. Clinical Performance Data

No data from human clinical studies was included to support the substantial equivalence of the proposed Byte Aligner System.

9. Conclusion

The information included in this Traditional 510(k) supports the substantial equivalence of the proposed Byte Aligner System with the predicate device Byte Aligner System (K180346). The proposed device has the same intended use and indications for use as the predicate device, and is an aligner system fabricated by thermoforming PETG (copolyester) plastics that induce tooth movement by orthodontic force application using continuous gentle forces.

The proposed device represents an extension of predicate device Byte Aligner System (K180346) by allowing for the addition of alternate PETG (copolyester) materials to be used for manufacturing of aligners and removing the shelf life of the device based on the nature of the Byte Aligner System and well-known polymer science. The technological differences between the predicate device Byte Aligner System (K180346) and the proposed device are supported with the data included in premarket notifications of reference devices Sureclear aligners (K171860) and Mouthguard and Aligner materials (K062828) and additional data provided in this submission in support of the equivalency between the polyester materials. In addition, this premarket submission incorporates slits and cut-outs into the aligner and allows for the use of attachments which is similar to the additional reference devices (K181739, K182826).

Based on the intended use, indications for use, and technological features comparison, and the review of literature, data on file, and testing by reference, it can be concluded that the proposed Byte Aligner System is substantially equivalent to the predicate device Byte Aligner System (K180346).