April 15, 2026

Dentsply Sirona, Inc.
Brianne Yaryan
Regulatory Affairs Specialist
211 W. Philadelphia St.
Suite 60w
York, Pennsylvania 17401

Re: K260722
Trade/Device Name: SureSmile Aligner (ASSY500020)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: March 5, 2026
Received: March 5, 2026

Dear Brianne Yaryan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

FDA Bobak Shirmohammadi - S

For Michael E. Adjodha, M.ChE., 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)*
K260722

Device Name
SureSmile Aligner (ASSY500020)

Indications for Use *(Describe)*
SureSmile Aligners are indicated for the orthodontic treatment of malocclusion.

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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K260722 - 510(k) SUMMARY
for
SureSmile Aligner

1. Submitter Information:

Name:	Dentsply Sirona
Address:	221 West Philadelphia Street, Suite 60W York, PA 17404
Contact Person:	Brianne Yaryan
Telephone Number:	+1(386)-290-5499
Email Address:	brianne.yaryan@dentsplysirona.com

Date Prepared:	March 5, 2026

2. Device Name:

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

3. Predicate & Reference Devices:

Table FS.1 Predicate Device Information

Device Name	Device Type	510(k)	Company Name
Nuvola Aligner	Predicate	K222418	Gruppo Europeo Ortodonzia srl (GEO S.r.l.)

Table FS.2 Reference Device Information

Device Name	Device Type	510(k)	Company Name
Sureclear Aligners	Reference	K171860	OraMetrix (part of Dentsply Sirona), now Dentsply Sirona Orthodontics Inc.

4. Description of Device:

SureSmile Aligners are removable orthodontic devices intended for the controlled movement of teeth to correct malocclusion. They are fabricated from clear, thin thermoformed plastic into a sequential series of aligners that reposition the teeth progressively over time. The device operates on the principle of sequential tooth movement through the application of low, continuous mechanical force transmitted from the aligner material to the dentition. The cumulative effect of consecutive aligner stages results in progressive repositioning of teeth toward the targeted tooth positions.

The SureSmile Aligner uses the SureSmile Software (originally cleared K002620, updated K253565) for digital treatment planning. The clinician uploads the patient's dental scans to the treatment planning software and enters a prescription for the final targeted tooth positions (a "setup"). By dividing the total planned movements from the starting malocclusion to the targeted tooth position into a series of intermediate "stages," the timing and duration of treatment is established. The clinician must review and approve the treatment plan prior to device production. The STL file output of the treatment planning software is used to create a model of the patient's teeth, which is then used to thermoform the aligners.

The aligners are thermoformed on the 3D models with transparent, biocompatible, thermoplastic materials that provide dimensional stability, resilience, and flexibility, ensuring adequate force delivery. The materials and manufacturing processes used for the subject device are the same as those in K171860.

When received, the aligner design and fit are confirmed by the treating clinician. Over a period of months, additional aligners are provided sequentially to the patient by the clinician to gradually move the target teeth to the desired positions. Treatment progresses by moving through the prescribed sequence of aligners, which are typically replaced every 1 to 2 weeks. Compliance to the prescribed wear time is critical for achieving the intended tooth movement during treatment.

5. Indications for Use:

SureSmile Aligners are indicated for the orthodontic treatment of malocclusion.

6. Substantial Equivalence Discussion:

The SureSmile Aligner is functionally equivalent to the Nuvola Aligner. Table FS.3 below demonstrates that the indications for use, in use duration, and the functional characteristics of the SureSmile Aligner are substantially equivalent to its predicate device.

7. Comparison of Indications for Use to Predicate:

The indications for use of the SureSmile Aligner is the same as that of the Nuvola Aligner. Therefore, the SureSmile Aligner's indications can be considered substantially equivalent to its predicate device.

8. Comparison of Technological Characteristics:

Based on the comparison below, the design, materials, in use duration, and performance characteristics of the SureSmile Aligner are very similar, and in many cases the same, to that of the Nuvola Aligner. Therefore, the technical characteristics of SureSmile Aligner can be considered substantially equivalent to its predicate device. For any difference from the predicate device, the subject device demonstrates equivalence to the technological characteristics of the reference device, the Sureclear Aligner. This is demonstrated in Table FS.3 below.

Table FS.3: Comparison of the Subject, Predicate, and Reference devices

	Subject Device	Predicate Device K222418	Reference Device K171860	Comparison
Trade Name	SureSmile Aligner	Nuvola Aligner	SureClear Aligner	NA
Manufacturer	Dentsply Sirona, Inc	Gruppo Europeo Ortodonzia srl (GEO S.r.l.)	Orametrix, Inc	NA
Common Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same as predicate and reference device
Regulation	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same as predicate and reference device
Device Class	II	II	II	Same as predicate and reference device
Product Code	NXC	NXC	NXC	Same as predicate and reference device
Indications for Use	SureSmile Aligners are indicated for the orthodontic treatment of malocclusion.	Nuvola Aligner is indicated for the orthodontic treatment of malocclusion.	Sureclear™ aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition.	Same as Predicate; similar to reference device. The reference device is the current version of the SureSmile Aligner. This submission removes 'in patients with permanent dentition' from the indication for use.
In Use Duration	Aligners are worn for approximately 1-2 weeks of 20- 22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner	Aligners are worn for approximately 1-2 weeks of 20- 22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner	Worn daily by the patient for approximately 20 to 22 hours, except when performing dental hygiene and eating and drinking. The treatment plan (and time) varies by individual patient prescription.	Same as Predicate; similar to reference device. The reference device is the current version of the SureSmile Aligner. This submission clarifies the wear duration to be '1-2 weeks.'
Patient Population	Children, Adolescents and Adults	Children, Adolescents and Adults	Not Specified	Same as Predicate.
Single Patient	Yes	Yes	Yes	Same as predicate and reference device
OTC or Prescription (RX)	Rx Only	Rx Only	Rx Only	Same as predicate and reference device

	Subject Device	Predicate Device K222418	Reference Device K171860	Comparison
Operating Principle	Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward.	Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward.	Sequential aligners are made from elastic thermoplastic materials that apply continuous gentle force to the teeth.	Same as predicate and reference device
Device Description	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Orthodontic aligners fabricated from a clear, thin thermoformed plastic in a sequential series, individually customized for each patient based on a doctor's prescription to progressively reposition the teeth via gentle, corrective forces in the upper and lower dental arches.	Same as predicate and reference device
Appearance	Clear Aligner	Clear Aligner	Clear Aligner	Same as predicate and reference device
Materials Type	Thermoplastic polymer PET-G	Thermoplastic polymer PET-G	Thermoplastic polymer PET-G	Same as predicate and reference device
Material Properties	Acceptable materials properties established for use as aligner (polyethylene terephthalate glycol PET-G) [Essix ACE, Essix Plus] (K062828)	Acceptable materials properties established for use as aligner (polyethylene terephthalate glycol PET-G) Erkodur (K200125)	Acceptable materials properties established for use as aligner (polyethylene terephthalate glycol PET-G) [Essix ACE, Essix Plus] (K062828)	Same as reference device, similar to predicate device
Manufacturing Process	Thermoforming on Models	Thermoforming on Models	Thermoforming on Models	Same as predicate and reference device
Treatment Software	SureSmile Software (K002620, K253565)	3Shape Ortho System (K152086) & Nuvola® Web	SureSmile Software (K002620)	Same as reference device, similar to predicate device. All are treatment planning software.
Attachments/ Modifications	Attachments, slits, and cut outs	Attachments, slits, and cut outs	Attachments, slits, and cut outs	Same as predicate and reference device
Anatomical Site	Mouth; mucosal membranes	Mouth; mucosal membranes	Mouth; mucosal membranes	Same as predicate and reference device
Biocompatibility	ISO 10993-1 ISO 10993-5:2009 Cytotoxicity ISO 10993-10:2021 Sensitization ISO 10993-23:2021 Irritation	ISO 10993-1 ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization/ Irritation	ISO 10993-1 ISO 10993-5 Cytotoxicity ISO 10993-18 Chemical Analysis	Same as predicate and reference device.

	Subject Device	Predicate Device K222418	Reference Device K171860	Comparison
	ISO 10993-11:2017 Material Mediated Pyrogenicity ISO 10993-11:2017 Acute Systemic Toxicity ISO 10993-3:2014 Genotoxicity ISO 10993-18 Chemical Characterization			

9. Non-Clinical Performance Data

A biocompatibility evaluation in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23, ISO 10993-11, ISO 10993-11, ISO 10993-3, ISO 10993-3, ISO 10993-18 was performed, and it was determined that no additional testing was required to demonstrate biological safety of subject devices.

10. Clinical Performance Data

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

11. Conclusion

The purpose of this Traditional 510(k) Premarket notification is to gain U.S. Premarket clearance to update the indications for use of the SureSmile Aligner, originally cleared as the Sureclear Aligner System (K171860), to remove 'in patients with permanent dentition' from the end of the indications for use statement, making the proposed indications for use statement substantially equivalent to the predicate Nuvola Aligner (K222418). As this is a labeling only change, all other characteristics of the subject device remain the same as the currently marketed SureSmile Aligner, which is included in this submission as a reference device.

The subject device SureSmile Aligners and the predicate device Nuvola Aligner have the same or similar technological characteristics, while the indications for use, in use duration, patient population, and operating principle are the same. Based on the comparison above, it can be concluded that the subject device is substantially equivalent to the predicate device Nuvola Aligner.