March 4, 2026

Dentsply Sirona, Inc.
John Van Hoven
Regulatory Affairs Manager
221 W. Philadelphia St.
York, Pennsylvania 17401

Re: K253565
Trade/Device Name: SureSmile Software
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: November 17, 2025
Received: November 17, 2025

Dear John Van Hoven:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253565

Please provide the device trade name(s).

SureSmile Software

Please provide your Indications for Use below.

The SureSmile Software is indicated for use as a front-end device for management of orthodontic models, systematic inspection, detailed analysis, treatment planning and simulation and the design of custom appliance systems, which may include sequential aligners, retainers, IDB trays, brackets, or wires, and dental casts. These applications are based on 3D models of the patient's dentition before the start of the orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.
The use of the SureSmile Software requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253565 - 510(k) SUMMARY
SureSmile Software

1. Submitter Information:

Name:	Dentsply Sirona Orthodontics Inc.
Address:	221 West Philadelphia Street, Suite 60W York, PA 17404
Contact Person:	John Van Hoven
Telephone Number:	+1(941)554-5276
Email address:	john.vanhoven@dentsplysirona.com

Date Prepared: February 24, 2026

2. Device Name:

Proprietary Name:	SureSmile Software
Common Name:	Orthodontic Appliance Treatment Planning Software
Classification Name:	Orthodontic Plastic Bracket
CFR Number:	21 CFR 872.5470
Device Class:	2
Product Code:	PNN

3. Predicate Device:

Table FS.1: Predicate device information

Predicate Device	510(k)	Company Name
ArchForm Orthodontic Software System	K213916	ArchForm, Inc.

Table FS.2: Reference device information

Reference Device Name	510(k)	Company Name
3Shape Ortho System	K171634	3Shape A/S
Spark Clear Aligner System	K203737	Ormco Corporation

4. Description of Device:

The **SureSmile® Software** is suitable for use for patients requiring orthodontic treatment; it allows the user to plan therapy and then order patient matched orthodontic appliances. The software includes many features to support diagnosis, planning, appliance design and treatment tracking. Additionally, SureSmile Software acts as the order management system for all SureSmile Digital Lab services and appliance production. SureSmile Software contains features to support ordering and shipment tracking. The software does not have any contact with the body.

5. Indications for Use:

The SureSmile Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment planning and simulation and the design of custom appliance systems, which may include sequential aligners, retainers, IDB trays, brackets, or wires, and dental casts. These applications are based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the SureSmile Software requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

6. Substantial Equivalence Discussion:

The SureSmile Software is functionally equivalent to the ArchForm Orthodontic Software System (K213916). **Table FS.3** below demonstrates that the functional characteristics of the SureSmile Software are substantially equivalent to its predicate device.

7. Comparison of the Indications for Use to Predicate Devices:

Based on the comparison found in Table FS.3, the Indications for Use statement of the SureSmile Software is the same as that of the ArchForm Orthodontic Software System. The treatment planning capabilities of the SureSmile Software is inclusive of orthodontic sequential aligners, retainers, IDB trays, brackets, wires, and dental casts, all of which are also included for the predicate device and / or reference devices. Therefore, the SureSmile Software can be considered substantially equivalent to its predicate device.

8. Comparison of Technological Characteristics:

Based on the comparison found in Table FS.3, the design, construction, and performance characteristics of the SureSmile Software is very similar, and in many cases the same, to that of the ArchForm Orthodontic Software System. The technological features of the SureSmile Software are the same or similar to the technological features of the predicate and / or reference devices. Therefore, the SureSmile Software can be considered substantially equivalent to its predicate device.

9. Non-Clinical Performance Data:

Utilizing FDA Guidance document “Content of Premarket Submissions for Device Software Functions” (issued June 14, 2023), the SureSmile Software underwent appropriate integration and other performance testing. The software passed the testing and performed per its intended use. The conclusions drawn from the nonclinical tests demonstrate that the proposed device is substantially equivalent to the identified legally marketed predicate device, K213916.

10. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the proposed SureSmile Software.

Table FS.3: Comparison of proposed, predicate and reference devices.

Device Name / 510(k)	SureSmile Software	ArchForm Orthodontic Software System (K213916)	3Shape Ortho System (K171634)	Spark™ Clear Aligner System (K203737)	Substantial Equivalence
	Proposed Device	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	
Manufacturer	Dentsply Sirona Orthodontics Inc	ArchForm, Inc	3Shape A/S	Ormco Corporation	N/A
Class	II	II	II	II	Same as predicate.
Classification Regulation	872.5470	872.5470	872.5470	872.5470	Same as predicate.
Product Code	PNN	PNN, LLZ	PNN, LLZ	NXC, PNN	Same as predicate.
Common Name	Orthodontic Plastic Brackets (Software)	Orthodontic Plastic Brackets (Software)	Orthodontic Plastic Brackets (Software)	Orthodontic plastic bracket	Same as predicate.
Indications for Use, User Population					
Indication for Use	The SureSmile Software is indicated for use as a front-end device for management of orthodontic models, systematic inspection, detailed analysis, treatment planning and simulation and the design of custom appliance systems, which may include sequential aligners, retainers, IDB trays, brackets, or wires, and dental casts. These applications are based on 3D models of the patient's dentition before the start of the orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the SureSmile Software requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	ArchForm Orthodontic system is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the ArchForm Orthodontic Software System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software	3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	Spark™ Software System: The Spark™ Software System is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays, retainers or bracket bonding templates based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Spark™ Clear Aligner System and Spark™ Software System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.	Same as predicate and reference devices. The subject device is inclusive of sequential aligners, retainers, IDB trays, brackets, wire, and dental casts, all of which are also included for the predicate and/or reference devices.

Device Name / 510(k)	SureSmile Software	ArchForm Orthodontic Software System (K213916)	3Shape Ortho System (K171634)	Spark™ Clear Aligner System (K203737)	Substantial Equivalence
	Proposed Device	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	
Supported Anatomic Areas	Maxilla, Mandible	Maxilla, Mandible	Maxilla, Mandible	Not Specified	Same as predicate.
OTC / Prescription (Rx) Device	Rx	Rx	Rx	Rx	Same as predicate.
Digital Lab / Technician Services	Yes	N/A	N/A	Yes	Same as reference device 2.
Minimum Hardware/Software Requirements					
CPU:	Intel Core i3	Intel 2nd Gen Core i5 processor or equivalent	Intel Core i5 or equivalent	Not Specified	Similar to predicate.
RAM:	8 GB	4 GB	8 GB	Not Specified	Same as reference device 1.
Hard Drive Space:	128 GB	128 GB	HDD Space: 250 GB	Not Specified	Same as predicate.
Resolution:	1440x900	1280x720	1280x800 or similar	Not Specified	Similar to predicate.
Video Card:	NVIDIA Quadro; Intel HD Graphics 5000	HD620	NVIDIA GeForce or NVIDIA Quadro[2]	Not Specified	Similar to predicate.
OS:	Windows 10 professional 64 bit, Mac OS X (current)	Windows 10, Mac OS Catalina	OS: Windows 7,8 or 10; 64 bit	Not Specified	Same as predicate and reference device 1.
Support Images	STL, DICOM	STL	STL, DICOM, PNG, JPG, BMP,	STL, DICOM	Same as predicate and reference devices.
Software Feature Comparison					
Manages patient & case base data	Yes	Yes	Yes	Yes	Same as predicate.
Collects study material	Yes	Yes	Yes	Yes	Same as predicate.
Segments study material	Yes	Yes	Yes	Not Specified	Same as predicate.
Aligns study material	Yes	Yes	Yes	Yes	Same as predicate.
Measures study material	Yes	Yes	Yes	Yes	Same as predicate.
Measures point selection	Yes	Not Specified	Yes	Not Specified	Same as reference device 1.
Analyzes study material	Yes	Yes	Yes	Yes	Same as predicate.
Prepares treatment simulations and options	Yes	Yes	Yes	Yes	Same as predicate.

Device Name / 510(k)	SureSmile Software	ArchForm Orthodontic Software System (K213916)	3Shape Ortho System (K171634)	Spark™ Clear Aligner System (K203737)	Substantial Equivalence
	Proposed Device	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	
2D Simulation	Yes	Not Specified	Yes	Not Specified	Same as reference device 1.
3D Simulation	Yes	Yes	Yes	Yes	Same as predicate.
Orthodontic Appliance Search	Yes	Not Specified	Yes	Not Specified	Same as reference device 1.
Orthodontic Appliance Virtual Preparation	Yes	Not Specified	Yes	Yes	Same as predicate.
Virtual Appliance Design	Yes	Yes	Yes	Yes	Same as predicate and reference devices.
Orthodontic Appliance Export	Yes	Yes	Yes	Yes	Same as predicate.

11. Conclusion

The SureSmile Software is an orthodontic treatment planning software. The SureSmile Software has the same intended use, incorporates the same fundamental technology and indications for use as the predicate ArchForm Orthodontic Software System (K213916) and the reference devices (K171634 & K203737). Based on the comparison of the indications for use, technological features, and software testing, the SureSmile Software has been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate device.