June 2, 2021

Sms Opco, LLC
% Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K210652
Trade/Device Name: 6MS Invisible Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 19, 2021
Received: April 21, 2021

Dear Patsy Trisler:

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/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 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 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,

For Michael E. Adjodha
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210652

Device Name

6MS Invisible Aligner

Indications for Use *(Describe)*

6MS Invisible Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars). The 6MS Invisible Aligner 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 – K210652

Submitter Name:	SMS OPCO, LLC
Submitter Address:	672 Morning Star Drive, Suite 120 The Colony, Texas 75056
Phone Number:	866-957-7645
Contact Person:	Mr. Bruce Page, QA/RA Manager
Date Prepared:	April 19, 2021
Device Trade Name:	6MS Invisible Aligner
Common Name	Aligner, Sequential
Classification Name Number Product Code Regulatory Class	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Primary Predicate Device:	K182826, Ormco™ Spark Aligner System, Sybron Dental Specialties
Reference Device:	None
Indications for Use	6MS Invisible Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars). The 6MS Invisible Aligner positions teeth by way of continuous gentle force.
Device Description, Mechanism of Action and Summary of Technological Characteristic	6MS Invisible Aligner consists of a series of dental-clinician prescribed customized clear plastic removable orthodontic aligner trays that are made from a clear, thin thermoformed polyurethane-polyester composite. The aligners are designed to gradually move the patient's teeth incrementally, repositioning them from their original misalignment to a more aligned state. This occurs through forces applied by the appliance to the teeth over time until final correction, according to the dental clinician's prescription has been achieved. A dental clinician prescribes the 6MS Invisible Aligner based on an evaluation of the patient's teeth. Either intraoral scans or physical impressions of the patient's teeth are taken, after which the clinician determine course of treatment with the system. The clinician completes a prescription form using standard dental software used for tooth alignment. The series of plastic aligner trays are designed according to commercially available dental software for planning the tooth alignments. After the digital plan is developed and approved by the prescribing dental clinician, SMS OPCO produces the aligner trays. The customized aligner trays are then provided to the dental clinician who distributes them to the patient assuring fit and function.

The clear, thin, thermoplastic polyurethane-polyester composite resin material used for fabrication of the 6MS Invisible Aligners is commonly used in many dental and orthodontic appliances, including the predicate clear aligners.

Technological Comparison:

The subject device is compared to the Predicate, K182826 in the comparison table on the final page of this Summary. It shows the following:

- Intended use: Same
- Thermoplastic material composition: Same
- Mechanism of Action: Same
- Biocompatible according to ISO 10993 requirements: Same
- Design of aligners: Similar
- Method used to manufacture the customized aligners by thermoforming: Similar
- Software use during design and manufacturing: Similar
- Process validation testing: Similar

The differences in the specific manufacturing methods used, including the use of different design and manufacturing software products, and the variability in the manufacturing process validation testing, do not raise new questions of safety and effectiveness.

Substantial Equivalence Comparison Table

	Subject Device: 6MS Invisible Aligner	**Predicate Device:** Ormco™ Spark™ Aligner System	**Comparison**
510(k) Number	**K210652**	**K182826**	N/A
Manufacturer	SMS OPCO, LLC	Sybron Dental Specialties	N/A
Classification # and Name Product Code Class	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	Same
Indications for Use	6MS Invisible Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars). The 6MS Invisible Aligner positions teeth by way of continuous gentle force.	The Ormco Spark 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 Intended Use
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Same, alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Same Mode of action
Description of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.	Same, each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.	Same Use
Material	Thin thermoplastic sheet of polyurethane polyester composite resin	Thin thermoplastic sheet of polyurethane polyester composite resin	Same material
Biocompatible	Meets ISO 10993-1, -5, -10 requirements: Cytotoxicity, Sensitization-Irritation, Intracutaneous Reactivity	Meets ISO 10993-1, -5, -10 requirements: Cytotoxicity, Sensitization-Irritation, Intracutaneous Reactivity	Same
Manufacturing Process	Thermoforming on molds	Thermoforming on molds	Similar method
Software Used for Treatment Planning and Manufacturing	3Shape K180981 and NemoCast K193003	Spark Aligner Software	Similar - Software products are different, but designed to perform similar functions
Non-Sterile Packaging	Yes	Yes	Similar - Exact packaging of Predicate is unknown
OTC or Rx	Rx	Rx	Same
Single Use	Yes	Yes	Same

Device Testing

Non-clinical Testing

Test data were submitted to:

- assure the mechanical properties of the aligner material meet specifications for up to 5 years shelf life [according to ASTM D638 standard's testing for: tensile strength (PSI); elongation (%), tensile@ yield (PSI), elongation @ yield (PSI) and tensile modulus (PSI)];
- assure the aligner material packaging retains the required moisture barrier properties;
- validate the processes used for the design and manufacture of the customized aligners, to ensure consistency between the aligner's design and the manufactured aligners.

All testing met the pre-determined acceptance criteria.

Biocompatibility

The thermoplastic polyurethane used for making the aligner series has been tested according to Good Laboratory Practices for its biocompatibility according to ISO 10993, as follows:

Part 5 (Cytotoxicity Elution - MEM),
Part 10 (Intracutaneous/Intradermal Reactivity),
Part 10 (Oral Mucosa Irritation),
Part 10 (Maximization for Delayed-Type Hypersensitivity)

In addition, the finished customized aligner was tested according to ISO 10993, Part 5, Cytotoxicity. Results show it is non-cytotoxic. All testing showed that the thermoplastic material and the manufactured finished aligner met the requirements of the test methods and are safe and biocompatible for the stated intended use.

Clinical Testing

Neither animal nor human testing are required for this product because it is composed of the same materials, is designed similarly, and is manufactured by a similar method as the predicate device.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and effective as the legally marketed device, K182826.