November 4, 2021

Ortho Lab Services, LLC
℅ Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K212496
Trade/Device Name: Ortho Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: August 6, 2021
Received: August 9, 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, M.ChE.
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)*
K212496

Device Name

Ortho Aligner System

Indications for Use *(Describe)*

The Ortho Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Ortho 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 – K212496

SUBMITTER	
Submitter Name:	Ortho Lab Services, LLC
Submitter Address:	251 Little Falls Wilmington, DE 19808
Contact Person: **Telephone:**	Zuzana Huelsbusch, Regulatory Director 0049-1573-0655-886
Date Prepared:	October 28, 2021
DEVICE	
Device Trade Name:	Ortho Aligner System
Common Name:	Aligner, Sequential (Clear Braces)
Classification Name **Number** **Product Code** **Regulatory Class**	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Review Panel	Dental
PREDICATE DEVICE	K172765, Smart Moves Complete, Great Lakes Orthodontics, Ltd.
INDICATIONS FOR USE STATEMENT	The Ortho Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Ortho Aligner System positions teeth by way of continuous gentle force.
DEVICE DESCRIPTION	The Ortho Aligner System is comprised of a series of clear, thin, thermoformed removable aligner trays that are designed to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology. The aligners are provided non-sterile and are customized for each patient according to the dental practitioner's prescription. Physical impressions or digital intraoral scans of the patient's teeth are provided to Ortho Lab Services. A treatment plan consisting of 3D models is created from the impressions or scans, by Ortho Lab Services using the OrthoWare software. Upon approval of the treatment plan by the treating dental practitioner using OrthoPortal and issuance of an electronic prescription, the clear aligners are manufactured using thermoforming methods. The finished, customized aligners are shipped based on the dental practitioner's order and confirmed for patient fit and design. The aligner trays are held in place by pressure and can be removed by the patient at any time.

MECHANISM OF ACTION	Each aligner in sequence applies the pressure (continuous force) on the teeth targeted to be repositioned in that step. Once the prescribed treatment period is concluded, the next set of aligner trays is used; this continues until the realignment goal has been met. The patient wears the thermoformed aligners for the prescribed time in sequence, as monitored and guided by the clinical/dental practitioner.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	Materials The thermoplastic materials used for the manufacture of the Ortho Aligners is the same material type which is used to make the Predicate Smart Moves Complete aligners, a PET-G thermoplastic sheet. Design The subject aligners are designed using similar methods and similar design software as the Predicate. Ortho Lab Services uses their OrthoWare software, which is similar to the Predicate manufacturer's Smart Moves Complete 3-D software. Manufacturing Process The process used to manufacture the Ortho Aligner System is thermoforming the material on a model (or mold), the same process method as used by the Predicate device manufacturer.
SAFETY TESTING	Biocompatibility: Testing of the plastic thermoformable material was performed for the material supplier by a contract test laboratory according to Good Laboratory Practices and to meet the requirements of ISO 10993-1 and Part 5 (Cytotoxicity) and Part 10 (Sensitization). In addition to the material biocompatibility, the submitter contracted to have testing performed according to ISO 10993-5 (Cytotoxicity) of the finished thermoformed aligner. All biocompatibility testing passed the test requirements.
PERFORMANCE TESTING	Software Verification and Validation Testing Software V & V testing, using FDA's guidance document, confirmed acceptance to required specifications. Bench testing Testing to validate the manufacturing process was performed. The test results ensured the accuracy of the final thermoformed aligner compared to the initial digital scans. Aligners met the specifications of the testing. *In vivo* Animal and Human Clinical Animal and human performance testing are not required for this device category.

COMPARISON TO THE PREDICATE DEVICE	The Ortho Aligner System has the same intended use as the predicate device. There are no fundamental technological differences between the subject and Predicate device. The differences, listed below, do not raise new types of safety and effectiveness questions: • The materials are of the same type: biocompatible PET-G sheets, developed for use by dental device manufacturers for fabricating customized dental appliances, including aligners. • The software products used for design of the subject and Predicate devices are different, but have the same purpose and are used in a similar way to design the treatment plans for tooth movement. They both use digital scans to generate images of the final treated states, and intermediate steps to achieve the final state, and convert those files to produce the series of customized aligners. • The manufacturing process methods are different but similar: both use standard methods and equipment to thermoform the designed aligners.
CONCLUSION	The conclusions drawn from the side-by-side comparison and the nonclinical testing presented in the 510(k), demonstrate that the subject Ortho Aligner System is as safe and effective, and thus substantially equivalent to, the legally-marketed Smart Moves Complete Predicate.

Substantial Equivalence Comparison Table

	Subject Device	Predicate Device K172765	Comparison
Device Name	Ortho Aligner System	Smart Moves Complete	N/A
Manufacturer	Ortho Lab Services, LLC	Great Lakes Orthodontics Ltd	N/A
Classification Regulation # 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	The Ortho Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Ortho Aligner System positions teeth by way of continuous gentle force.	Smart Moves Complete is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Smart Moves Complete positions teeth by way of continuous gentle force.	Same
Mode of Action	The appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	The appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	Same
Description of Use	Each removable preformed plastic tray is worn by the patient as prescribed by the doctor, usually a few weeks prior to using the next sequential aligner tray.	Each removable preformed plastic tray is worn by the patient as prescribed by the doctor, usually a few weeks prior to using the next sequential aligner tray.	Same
Material	Thermoplastic PETG	Thermoplastic PETG	Same material type
Manufacturing Process	Thermoforming on models	Thermoforming on models	Same process, similar methods
Software Used	Yes, for treatment planning and design of sequential trays by Ortho Lab Services.	Yes, for treatment planning and design of sequential trays.	Same purposes; Similar software
Prescription Use	Rx	Rx	Same
Single Patient Use	Yes	Yes	Same
Biocompatibility	Meets ISO 10993-1, -5, -10 requirements: Cytotoxicity and Sensitization/Irritation	Meets ISO 10993-1, -5, -10 requirements: Cytotoxicity and Sensitization/Irritation	Same
Process Flow Validation Testing	Performed testing to validate the finished device matches the software output design.	Performed testing to validate the finished device matches the software output design.	Same