July 14, 2022

Ordont Orthodontic Laboratories, Inc.
% Patsy Trisler
Regulatory Consultant
Trisler Consulting, dba
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K221097
Trade/Device Name: SmileSeries
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 13, 2022
Received: April 14, 2022

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221097

Device Name

SmileSeries™

Indications for Use *(Describe)*

The SmileSeries™ is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in adult and adolescent patients with permanent dentition (i.e. all second molars). The SmileSeries™ 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.

SECTION 5

510(k) SUMMARY

SUBMITTER	
Submitter Name:	Ordont Orthodontic Laboratories, Inc.
Submitter Address:	
Contact Person: **Email:** **Telephone:**	Paul Ruzicka, CDA Paul@ordont.com 800-325-3698
Date Prepared:	April 13, 2022
DEVICE	
Device Trade Name:	SmileSeries™
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	Primary Predicate: K202857, ClearPath Aligner, ClearPath Orthodontics Reference Device: K180941 Ortho System™, 3Shape A/S
DEVICE DESCRIPTION	The SmileSeries™ 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. SmileSeries™ aligners are provided non-sterile and are customized for each patient according to the dental clinician's prescription. The dental health professional (dentist/orthodontist) takes provides physical or scanned impressions of the patient's teeth to SmileSeries™. A digital setup of either the scanned impression or a scan of the physical impression is sent to the clinician for approval. Upon approval, molds are then created with 3D-printing technology and the clear aligners are thermoformed on the molds and laser marked. The finished, customized aligners are provided to the dental health care professional who provides them to the patient, confirming fit and design. The aligner trays are held in place by pressure and can be removed by the patients at any time.

MECHANISM OF ACTION	Each aligner in the set is used for the specified period of time, usually 2-3 weeks, to exert gentle force to achieve progressive realignment of the teeth until the final correction has been achieved. The daily treatment time is usually 22 hours, or except during eating, based on the clinician's prescribed treatment plan.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The thermoplastic material used for the manufacture of the SmileSeries™ aligner is the same material used to make the predicate ClearPath Aligner. The software system used is Ortho Analyzer, 2019 ver 1.8.1.0 by 3Shape A/S (Reference device - K180941). It also is the same as used for the Predicate. It is used for management of 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements, and design of orthodontic appliances based on 3D scanned orthodontic models.
INDICATIONS FOR USE STATEMENT	The SmileSeries™ is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in adult and adolescent patients with permanent dentition (i.e. all second molars). The SmileSeries™ positions teeth by way of continuous gentle force.
SAFETY TESTING	Biocompatibility: Testing of the plastic thermoformable material used to make the SmileSeries™ aligners has been provided in previous 510(k) submissions to FDA.
PERFORMANCE TESTING	Bench testing was performed to validate the manufacturing process, to ensure the accuracy of the final thermoformed aligner compared to the initial digital scan. A final report was part of the 510(k) package. In vivo Animal and Human Clinical performance testing are not required for this device category.
COMPARISON TO THE PREDICATE DEVICE	The SmileSeries™ aligner has the same intended use as the predicate device. The thermoplastic material is the same and the design phase makes the use of the same software as the predicate. The manufacturing fabrication of the clear aligner makes use of similar, industry-standard processes with the same or similar machines and materials. Any differences in the specific company processes do not raise new questions of safety and effectiveness.
SUBSTANTIAL EQUIVALENCE CONCLUSION	The information and data provided in this 510(k) establish that the SmileSeries™ is substantially equivalent to the predicate ClearPath Aligner in the intended use, design, principle of operation, technology, and thermoformable material used to make the aligner. Comparison of all key parameters are presented in the following SE Comparison table

Substantial Equivalence Comparison Table

510(k) Number	Proposed Device K_____	Predicate Device K202857	Comparison
Device Name	SmileSeries™	ClearPath Aligner	N/A
Manufacturer	Ordont Orthodontic Laboratories, Inc.	ClearPath Orthodontics, Ltd	N/A
Classification **Regulation** **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 SmileSeries™ is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in adult and adolescent patients with permanent dentition (i.e. all second molars). The SmileSeries™ positions teeth by way of continuous gentle force.	The ClearPath Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The ClearPath Aligner positions teeth by way of continuous gentle force.	Same
Mode of Action	The removable appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	The removable appliance applies gentle forces on teeth according to the plan prescribed by the doctor	Same
Description of Use	Each removable preformed plastic tray, prescribed by the Dr, is worn by the patient usually for a few weeks, prior to using the next sequential aligner tray.	Each removable preformed plastic tray, prescribed by the Dr, is worn by the patient usually for a few weeks, prior to using the next sequential aligner tray.	Same
Material	Thermoformed plastic	Thermoformed plastic	Same
Manufacturing Process	Forming of plastic sheets on unique dental models using thermoforming machine	Forming of plastic sheets on unique dental models using thermoforming machine	Same
Software Used	Yes, for treatment planning and 3D printing of models.	Yes, for treatment planning and 3D printing of models.	Same
Prescription Use	Rx	Rx	Same
Biocompatibility	Yes, shown to meet requirements	Yes, shown to meet requirements	Same
Validation Testing	Yes, performed	Yes, performed.	Same