November 9, 2020

Drake Precision Dental Laboratory Inc
% Srinagesh Koushik
Managing Partner
BDRA Consulting LLC
1 Clearwater Court
Damascus, Maryland 20872

Re: K200005
Trade/Device Name: Concinnity Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 1, 2020
Received: October 2, 2020

Dear Srinagesh Koushik:

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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K200005

Device Name
Concinnity Aligners™

Indications for Use *(Describe)*
The Concinnity Aligners™ is intended for orthodontic treatment and correction of misaligned and maloccluded permanent teeth (i.e. all second molars).

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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510k Summary K200005

510k Owner:	Drake Precision Dental Laboratory INC
510k Owner Address:	Drake Precision Dental Laboratory INC 8510 Crown Crescent Ct. Charlotte, NC, 28227
Contact:	Robert Savage Vice President / Chief Financial Officer
Phone:	704-845-2401 Extension 1106
Email:	bsavage@drakelab.com
Submission Correspondent:	Shree Koushik Ph.D. RAC BDRA Consulting LLC 1 Clearwater Court, Damascus, MD 20872
Phone:	301-922-7231
Email:	shree@bdraqa.com
Date Prepared:	November 2, 2020
Device Trade Name:	Concinnity Aligners™
Classification Name:	Orthodontic Plastic Bracket
Common Name:	Sequential Aligner
Classification Number:	21 CFR 872.5470
Product Code:	NXC
Classification:	2
Predicate Device:	K173785, Custom Clear Aligners System Clearance date 03/13/2019
Reference Device:	K182826, Ormco Spark Aligner System Clearance Date: 10/11/2018

Intended Use / Indications for use:
The Concinnity Aligners™ is intended for orthodontic treatment and correction of misaligned *and maloccluded permanent teeth (i.e. all second molars).*

Device Description:

The Concinnity Aligners™ is a custom clear aligner system. They are a series of doctor (orthodontist or dentist) prescribed clear plastic removable aligners that are used as alternative to traditional orthodontic wires and brackets for the alignment of maloccluded or misaligned teeth. This series of aligner moves the teeth gently, and in small increments, from their original misalignment to their final treated position for improved dental alignment.

The Concinnity Aligners™ comes in two forms: a polyurethane-based material used to treat malocclusion in heavy bruxers, and a second form made from cycloaliphatic co-polyester polyurethane used in for all other patients. The polyurethane material is identical to the predicate device's material, and the cycloaliphatic co-polyester and polyurethane materials are used in the reference device.

The manufacturing of Concinnity™ Aligners begins with the clinician prescribing aligners to treat a patient's malocclusion. The decision to use clear aligner-based treatment is made by the clinician. In addition to the prescription the clinician also provides Drake Precision Dental Laboratory (DPDL) with a model of the patient's dentition. The clinician can generate a digital file by scanning the patient's mouth directly using Intraoral scanner (IOS) software, such as 3Shape Trios or iTero software. A mold of the patient's dentition is obtained using traditional impression material or by converting the mold to a stone model.

Impressions are taken by the dental clinician and submitted to Drake Labs along with the physician's prescription. All incoming impressions are logged and tracked under the DPDL QMS system. If DPDL receives a digital file it is tracked through its QMS system without any modifications. If DPDL receives a stone model from the clinician the information is entered and tracked as per QMS. The stone model is scanned using a digital scanner and converted into a digital file. Upon receipt of traditional impression molds, they are converted to stone models which can be scanned and digitized.

The digital files are sent to a third party design firm which develops the treatment plan. The third-party design firm utilizes the digital files and the prescription from the clinician to create a customized treatment plan that is reviewed and approved by the clinician. The customized plan generates a series of *.stl CAD files for building models that allow fabrication of aligners that gently move the teeth in small increments. The third party uses the 3Shape Clear Aligner Studio (K180941) to develop the treatment plan. The treatment plan is sent to the prescribing clinician for approval before it is sent back to DPDL.

Once DPDL receives these *.stl CAD files of the treatment plan the CAD unit in DPDL receives the documents, updates the QMS documentation and manufacturing begins. The DPDL manufacturing unit generates sequential 3D printed models replicating the clinician approved treatment plan. The sequential models are 3D printed and are used to generate clear thermoplastic aligners.

The aligners are cut to fit dentition, the cleaned and polished to remove rough edges. The sequential aligners are the packaged and labeled. Quality assurance ensures that the correct aligners are being shipped to the prescribing physician. The final product is released and shipped to the prescribing clinician who is responsible for ensuring the patient's safe use of the device.

The Concinnity™ Aligners are manufactured using thermoplastic polymers used by the predicate and reference devices. Manufacturing, processing, labeling, and shipping of the aligners are performed under strict quality control procedures that ensures Concinnity Aligners™ is manufactured under the QMS.

Drake Labs sends the aligners to the doctor who delivers them to the patient in sequential stages, provides instructions for use (such as when to change aligners), and monitors the case progression and fit and function from the first aligner through the end of treatment through follow-up appointments.

Operating Principle:
Each progressive aligner is intended to be worn for 2 weeks for 22 hours per day (removal only for eating and oral hygiene). Gentle force is applied (by the aligner) to achieve progressive realignment of the teeth until the teeth are aligned as per treatment plan. Similar to predicates and traditional braces the treatment plan proceeds over time under clinician supervision.

Biocompatibility testing:
The following biocompatible studies were performed on the thermoplastic polymers used to manufacture Concinnity Aligners:

Biocompatibility			
Number	Test	Standard	Results
1	Cytotoxicity	ISO 10993-5	Passed
2	Sensitization	ISO 10993-10	Passed
3	Intracutaneous reactivity	ISO 10993-10	Passed
4	Oral mucosal Irritation	ISO 10993-10	Passed
5	Genotoxicity	ISO 10993-3	Passed
6	Skin irritation	ISO 10993-10	Passed
7	Sub chronic systemic toxicity	ISO 10993-11	Passed

Biocompatibility evaluation conducted determined that the Concinnity Aligners™ are biocompatible for their intended use.

Bench Performance Testing:
Bay Materials LLC, the manufacturer of the thermoplastic aligner materials, have conducted extensive physical properties testing. DPDL conducted a manufacturing fit validation study using both material types.

Briefly, four complete orthodontic cases have been evaluated at several different intervals in the manufacturing process of the Concinnity Aligners™. The integrity of the printed models from the digital files was assessed at several stage intervals for accuracy and predictability of the printed models.

The digital model files were measured using the digital measurement tool within the 3shape software. The printed digital models, as well as the aligners, were measured using digital hand calipers. A licensed clinician then evaluated the clear aligner's quality for fit, function, and adaptability to the software treatment design models and the printed models.

The manufacturing fit validation process included the following steps: first, four different orthodontic cases that could be treated using Concinnity Aligners™ were selected. Next, after receiving the prescription and dental impression from the prescribing clinician, the subjects were documented as per the DPDL quality management system. Then, the digital files of the patient's impressions were sent to a third-party design firm. The design firm designed the treatment plan and obtained prescribing clinicians' approval. Finally, upon receipt of the treatment design files, DPDL 3D printed dental models of the first, middle, and last stages for each of the four cases. Aligners from both thermoplastic aligners were cast for the first, middle and last stages for the four cases.

The differences in distances between digital files, 3D models, and aligners were calculated and evaluated. The manufacturing fit validation study demonstrated the differences in distance measured were within statistically established tolerance limits. Furthermore, the aligner fit clinician evaluation showed that the aligners manufactured at each stage demonstrated that all test cases received a Grade A, passing all pre-determined evaluation criteria. No manufacturing inconsistencies could be found.

This study and the data included have demonstrated that Concinnity Aligners can be manufactured as intended.

Animal or Human testing:
Concinnity Aligners™ are composed of identical material components as the predicate devices, using similar manufacturing processes. They have the same intended use, including the same intended anatomical location and frequency and duration of use. Additionally, the material manufacturer conducted physical properties testing and provided the reports to FDA. Therefore, animal and human testing was not determined to be necessary.

Substantial Equivalence:

The Concinnity Aligner's intended use is identical to the predicate and reference device. They all are all made of the same materials, using similar manufacturing processes, and have identical clinical use. They also are used in the same intended anatomical location and have the same frequency and duration of exposure. Drake Precision Dental Laboratory concludes that

Concinnity Aligners™ is substantially equivalent to the predicate devices.

Substantial Equivalence Table:

Trade Name:	**Custom Clear Aligner System**	K182826	**Concinnity Aligners™**
	Primary Predicate	Reference Device	Subject Device
510(k) Number	K173785	K182826	
Manufacturer	Derby Dental Laboratory, Inc.	Sybron Dental Specialties	Drake Precision Dental Laboratory
Trade Name:	**Custom Clear Aligner System**	K182826	**Concinnity Aligners™**
Regulation Product Code Classification Classification Name	21 CFR 852.5470 NCX Class 2 Orthodontic Plastic Bracket	21 CFR 852.5470 NCX Class 2 Orthodontic Plastic Bracket	21 CFR 852.5470 NCX Class 2 Orthodontic Plastic Bracket
Intended Use / Indications for use	The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through the orthodontic treatment of misalignment and malocclusion.	The Ormco™ Spark™ Aligner 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.	The Concinnity Aligners™ is intended for orthodontic treatment and correction of misaligned and maloccluded permanent teeth *(i.e. all second molars*.
Operating Principle	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displaStone based on a doctor's prescription	Each progressive aligner is intended to be worn for 2 weeks / 22 hours per day (removal only for eating and oral hygiene), where gentle force is applied (by the aligner) to achieve progressive realignment of the teeth till the teeth are aligned as per treatment plan. Similar to predicates and traditional braces the treatment plan proceeds overtime under clinician supervision.
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks before using the next sequential aligner tray.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displaStone based on a doctor's prescription	Each sequential preformed plastic tray is worn by the patient as per prescriber instruction.

Material	Thin thermoformed polyurethane	Thermoplastic polyurethane - polyester composite resin	Identical to the predicate or reference device
Biocompatible	Yes	Yes	Yes
	Primary Predicate	Reference Device	Subject Device
OTC or Rx	Rx	Rx	Rx
Software Use for ordering workflow	Yes	Yes	Yes
Trade Name:	**Custom Clear Aligner System**	K182826	**Concinnity Aligners™**
Sterile	No	No	No