March 13, 2018

Derby Dental Laboratory
% Patsy Trisler
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Ave, #509
Chevy Chase, Maryland 20815

Re: K173785
Trade/Device Name: Custom Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: December 12, 2017
Received: December 13, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173785

Device Name

Custom Clear Aligner System

Indications for Use *(Describe)*

The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K173785

Submitter Name:	Derby Dental Laboratory, Inc.
Submitter Address:	3332 Gilmore Industrial Blvd Louisville, KY 40213
Phone Number:	800-745-6718
Contact Person:	Mr. Reed Nunnally
Date Prepared:	March 13, 2018
Device Trade Name:	Custom Clear Aligner System
Common Name	Aligner, Sequential
Classification Name Number Product Code Regulatory Class	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Primary Predicate Device:	K113618, ClearCorrect System, ClearCorrect LLC
Reference Predicate Device:	K152086, 3Shape Ortho System (3Shape A/S)
Statement of Intended Use	The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.
Device Description and Summary of Technological Characteristics	Derby Dental Laboratory's Custom Clear Aligner System contains a series of doctor-approved, customized processed, clear plastic removable aligners that gradually move the patient's teeth in small increments from their original misalignment to a more optimal, aligned and treated stated. Derby Dental Laboratory manufactures the customized aligners based on standard impressions sent to the company by the prescribing dentist or orthodontist. These are made after the clinician has assessed the patient's teeth, designed a treatment plan, and taken the impressions. Derby Dental manufactures models from the impressions and then scans the models using standard validated software. The digital files are used to produce the aligner series using standard thermoplastic polyurethane. The thermoplastic material used for fabrication of the aligners is commonly used in many dental appliances.

Mechanism of Action

In the same manner as the predicate device, each aligner exerts gentle force to achieve progressive realignment of the teeth until the final correction has been attained. This is based on the treatment plan and proceeds over time.

Device Testing

Biocompatibility

Contact of the device to the patient's oral tissue requires the aligner material to be biocompatible. The thermoplastic polyurethane has been tested according to Good Laboratory Practices for its biocompatibility according to ISO 10993, as follows:

Part 3 (Bacterial Mutagenicity – Ames Assay)
Part 5 (Cytotoxicity Elution - MEM),
Part 10 (Intracutaneous/Intradermal) Reactivity),
Part 10 (Oral Mucosa Irritation),
Part 10 (Maximization for Delayed-Type Hypersensitivity),
Part 11 (Subacute Systemic Toxicity)

The testing has shown that the material is biocompatible for the use intended.

Animal | Human Testing

No animal or human testing were required for this product because it is composed of the same materials and has a similar design and method of manufacture/fabrication in comparison to the predicate device.

Comparison to Predicate Device:

Trade Name:	**Custom Clear Aligner System**	**ClearCorrect System**
510(k) Number	K173785	K113618
Manufacturer	Derby Dental Laboratory, Inc.	ClearCorrect, LLC
Classification # & Product Code	21 CFR 852.5470 NXC 2	21 CFR 852.5470 NXC 2
Intended Use	The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Correct System positions teeth by way of continuous gentle
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.
Method 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.	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.
Material	Thin thermoformed polyurethane	Thin thermoformed polyurethane
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Software Use	Yes	Yes
Sterile	No	No

The intended use of the Custom Clear Aligner System is similar to that of the primary predicate device as they are both intended for correcting dental malocclusion in patients with permanent dentition.

It has a similar technological principle, and the device characteristics are similar to the predicate device. The mode of operation and the material used to fabricate the aligner trays is the same as the predicate device. There are no notable differences comparing Derby Dental's Custom Clear Aligner System to the predicate ClearCorrect System.

Substantial Equivalence Conclusion

Thus, based on the above it can be concluded that Derby Dental Laboratory's Custom Clear Aligner System is substantially equivalent to the predicate device.