Thursday, March 12, 2020

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

Re: K192338
Trade/Device Name: NEOLab Clear Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: February 21, 2020
Received: February 24, 2020

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 Srivinas ‘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)*
K192338

Device Name

NEOLab Clear Aligners

Indications for Use *(Describe)*

NEOLab Clear Aligners are indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). The NEOLab Clear Aligners position teeth through the use 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Name:	New England Ortho Lab, Inc.
Submitter Address:	3 Riverside Drive Andover, MA 01810
Phone Number:	1-800-922-6365
Contact Person:	Ms. Olivia Channon Document Control Coordinator
Date Prepared:	February 21, 2020
Device Trade Name:	NEOLab Clear Aligners
Common Name	Aligner, Sequential
Classification Name Number Product Code Regulatory Class	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Primary Predicate Device: Reference Devices:	K113618, ClearCorrect System, ClearCorrect, LLC K152086, Ortho System™, 3Shape A/S K180941, Ortho System™, 3Shape A/S
Indications for Use Statement	NEOLab Clear Aligners are indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). The NEOLab Clear Aligners position teeth through the use of continuous gentle force.
Device Description and Summary of Technological Characteristics	NEOLAB Clear Aligners consist of a series of customized clear plastic removable aligners that are fabricated from a clear, thin thermoformed polyurethane. The aligners are designed to gradually move the patient's teeth incrementally, repositioning them from their original misalignment to a more aligned state. The aligners, customized for each patient's prescription, are designed and manufactured based on either standard impressions or intraoral scans taken by the dental clinician and which are then sent to the company. The aligners are then sent back to the dental clinician who then distributes them in sequential stages to the patient and follows up with the patient through orthodontic examinations to check device fit and function. During manufacturing, models are made from physical impressions or intraoral scans. Those made from stone or plaster impressions are scanned into the computer and made into digital files. The intraoral scans arrive as digital files. The digital files are 3D printed and are used to produce the aligner series with the thermoplastic polyurethane.

	The thermoplastic material used for fabrication of the aligners is commonly used in many dental appliances, including the predicate aligners.
Mechanism of Action	Based on the clinician's treatment plan, each aligner is used for a defined period of time to exert gentle force to achieve progressive realignment of the teeth. This occurs over time until the final correction has been achieved.

Device Testing	<u>Laboratory/Bench Testing</u>
	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) – testing included:
	  ▪ tensile strength (PSI)
	  ▪ elongation (%)
	  ▪ tensile @ yield (PSI)
	  ▪ elongation @ yield (PSI)
	  ▪ 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.
	
	<u>Biocompatibility</u>
	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 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)
	Further, the finished customized aligner was tested according to ISO 10993, Part 5, Cytotoxicity. Results show it is non-cytotoxic.
	All testing showed that the material and manufactured aligner met the requirements of the test methods and are safe and biocompatible for the stated intended use.
	
	<u>Animal | Human Testing</u>
	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.

Comparison to Predicate Device:	There are no notable differences comparing the NEOLab clear aligner to the ClearCorrect predicate device: ▪ The intended use is the same. ▪ The mechanism of action is similar. ▪ The polyurethane material used to make the aligners is the same. ▪ The method of manufacture and customizing the aligners is similar. ▪ The use of software for planning and manufacturing are similar. Refer to the Substantial Equivalence Comparison table below for a side-by-side comparison of the indications for use, technological characteristics, materials and principles of operation.
Substantial Equivalence Conclusion:	As presented in the 510(k) and summarized herein, it can be concluded that NEOLab Clear Aligner is substantially equivalent to the predicate device.

Substantial Equivalence Comparison

Trade Name:	NEOLab Aligner System	ClearCorrect System
510(k) Number	K1923338	K113618
Manufacturer	New England Ortho Lab, Inc.	ClearCorrect, LLC
Classification # & Product Code Class	21 CFR 852.5470 NXC 2	21 CFR 852.5470 NXC 2
Indications for Use	NEOLab Clear Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The NEOLab Clear Aligners position teeth by way of continuous gentle force.	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 force.
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