January 6, 2021

New England Ortho Lab, Inc
Olivia Channon
Document Control Coordinator
3 Riverside Drive
Andover, Massachusetts 01810

Re: K203339
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: December 7, 2020
Received: December 7, 2020

Dear Olivia Channon:

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 Adjodha
Assistant 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: 06/30/2023
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.

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Special 510(k) Summary

Submitter Name	New England Ortho Lab, Inc
Submitter Address	3 Riverside Dr Andover, MA 01810
Phone Number	+1 (800) 922 – 6365
Contact Person	Ms. Olivia Channon Document Control Coordinator olivia@neolab.com
Date Prepared	December 2, 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 II
Primary Predicate Device	K182826, Ormco™ Spark™ Aligner System, Sybron Dental Specialties
Reference Devices	K152086, Ortho System™, 3Shape A/S K180941, Ortho System™, 3Shape A/S
Statement of Intended Use	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-polyester resin, and are intended to be worn 22 hours a day. 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 the clinical standard impressions or intraoral scans which are taken by the dental clinician and sent to the company by the prescribing dentist or orthodontist. Models, impressions, or intraoral scans may be used. Models and impressions are converted into a digital format using a standard validated software. The digital files are used to produce the aligner series with the thermoplastic polyurethane-polyester resin upon review and approval from the dental clinician. Once fabricated, the aligners are then returned to the dental clinician who then dispenses them to the

patient in sequential stage, and confirms fit and functions and monitors the patient through the entire course of aligner therapy. This summary of technological characteristics is unchanged from the predicate device.

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

Laboratory Testing

Test data were submitted to:

- Assure the aligner mechanical properties of the aligner material meet specifications for up to 5 years shelf life;
- Validate the processes used for the design and manufacture of the customized aligners.

Biocompatibility

The thermoplastic polyurethane-polyester resin 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.

This testing showed that the material and manufactured aligner met the acceptance criteria, passed the respective tests, and are safe and biocompatible for the stated intended use.

Comparison to Predicate Device

There are no notable differences comparing the NEOLab Clear Aligner to the Ormco™ Spark™ Aligner System predicate device:

- The intended use is the same;
- The mechanism of action is similar;
- The polyurethane-polyester 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 manufacture is similar.

Substantial Equivalence Conclusion

Based on the documentation presented in this Special 510(k), as summarized above, it can be concluded that NEOLab Clear Aligners are substantially equivalent to the predicate device.

Trade Name	NEOLab Clear Aligners	Ormco™ Spark™ Aligner System
510(k) Number	K203339	K182826
Submission	Special 510(k)	Traditional 510(k)
Manufacturer	New England Ortho Lab, Inc	Sybron Dental Specialties
Classification No.	21 CFR 852.5470	21 CFR 852.5470
Product Code	NXC	NXC
Class	II	II
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 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.
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays, fabricated based on doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on the doctor's prescription.
Process and Method of Use	Scans and prescription are sent to NEOLab by the doctor. Treatment is planned by NEOLab, and reviewed and approved by doctor. Aligners are fabricated and shipped to doctor. Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner.	Doctor uploads patient's dental scans into proprietary software; doctor uses software for case viewing and treatment planning; Ormco technician receives case and uses proprietary 3D software to generate models or the aligners based on the prescription (desired outcome); Doctor approves treatment plan and final treated state; manufacturer crafts and produces aligners; aligners and ships them to doctor, who them provides them to the patient, confirming fit and design.
Material	Thermoplastic polyurethane-polyester composite resin	Thermoplastic polyurethane-polyester composite resin
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Software Use	Yes	Yes
Sterile	No	No