February 11, 2020

uLab Systems, Inc.
% Sylvia Erickson
Regulatory Consultant
Sylvia Erickson Consulting
157 Ruby Avenue
San Carlos, California 94070

Re: K192596
Trade/Device Name: ULab Systems Dental Aligner Kit
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 3, 2020
Received: January 3, 2020

Dear Sylvia Erickson:

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)*
K192596

Device Name
uLab Systems Dental Aligner

Indications for Use *(Describe)*
The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

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

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information:

uLab Systems, Inc.
3 Lagoon Drive
Suite 180
Redwood City, CA 94065

Contact Person: Charlie Wen
Phone: 650-804-1397

Submission Correspondent:

Sylvia Erickson
Principal, Sylvia Erickson Consulting

Device Information:

Trade Name:	uLab Systems Dental Aligner Kit
Common Name:	Sequential Aligner
Classification Name:	Orthodontic Plastic Bracket
Classification Regulation:	21CFR 872.5470
Device Class:	II
Product Code:	NXC

Primary Predicate:

Ortho Caps GmBH Orthocaps Twinaligner, K180241

Reference Predicates:

Derby Dental Laboratory Custom Clear Aligner System, K173785
Sybron Dental Specialties Ormco Spark Aligner System, K182826
uLab Systems uDesign, K171295

Date Prepared:

February 10, 2020

Device Description:

The uLab Systems Dental Aligner Kit is an orthodontic treatment system, that consists of doctor-prescribed, clear, thin, plastic removable aligners. Patients are seen in a dental office where a dental professional (dentist/orthodontist) scans or takes a physical impression of the teeth, which is then used to fabricate the aligners. The aligners are designed and custom-made by dental professionals using uLab Systems proprietary technology. The aligners are made of aesthetic and medical grade materials chosen by doctors for their patients. During the orthodontic treatment, each preformed plastic aligner is worn in sequence by the patient as prescribed by the dental practitioner, moving the patient's teeth gradually to the ideal position.

Indications for Use:

The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:

The subject and predicate devices share the same intended use for alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

The subject and predicate device are based on the following same technological elements:

- Both devices are clear plastic sequential aligners.
- Both devices have the same intended use for alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.
- Both devices have the same indications for use.
- Both devices have the same principle of operation.
- Both devices are fabricated based on an orthodontic treatment plan designed by the aligner manufacturer's technicians from digital scans of the patient's teeth in an untreated state.
- Both devices are made of thermoplastic.

The only differences between the subject and device are the following:

- The subject device may alternatively be fabricated based on an orthodontic treatment plan designed by a dental practitioner.
- The subject device materials are the same material used in the reference predicates, whereas the primary predicate device material is an unspecified thermoplastic. The subject and primary predicate devices otherwise share the same technological characteristics.
- The subject device is not designated for use during a specific time of day.

Attribute	Subject Device uLab Systems Dental Aligner (uLab Systems)	Predicate Device Orthocaps Twinaligner (Ortho Caps GmBH) K180241
Indications for Use	The ULab System Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.	The Orthocaps TwinAligner® System is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.
Device Description	A series of custom-made removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.	A series of custom-made removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.
Principles of Operation	Each preformed plastic tray is worn in sequence by the patient as prescribed by the dental practitioner. Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Each preformed plastic tray is worn in sequence by the patient as prescribed by the dental practitioner. Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
Aligner Design Process	Dental software, the uLab Systems uDesign, K171295, for tooth alignment uses digital scan (untreated state) to generate the image of a final, provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject, make or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of 3D models used to produce thermoformed aligners.	Standard dental software for tooth alignment uses digital scan (untreated state) to generate the image of a final, provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of 3D models used to produce thermoformed aligners.
Material	Zendura A (thin thermoformed polyurethane) or Zendura FLX (copolyester and polyurethane composite)	Thermoplastic
Features	Aligners made from different materials as prescribed by physician	Aligners made from different materials as prescribed by physician for daytime or nighttime use
OTC or Rx	Rx	Rx

Attribute	Subject Device uLab Systems Dental Aligner (uLab Systems)	Predicate Device Orthocaps Twinaligner (Ortho Caps GmBH) K180241
Sterilization	No	No

Performance Data:

The following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination:

- Biocompatibility testing for the aligner materials was completed in accordance with ISO 10993 per the following:
    - Part 5: Cytotoxicity Elution -MEM
    - Part 10: Intracutaneous/Intradermal Reactivity
    - Part 10: Maximimzation for Delayed-Type Hypersensitivity
    - Part 10: Oral Mucosa Irritation Test

  The test results demonstrate that the material is biocompatible for the intended use.

  Additionally, biocompatibility testing for the finished device was completed in accordance with ISO 10993 per the following:
    - Part 5: Cytotoxicity Elution -MEM

  The test results demonstrate the finished device is biocompatible for the intended use.
- Design verification and process validation testing was completed, demonstrating that the manufacturing process and finished device meet product requirement specifications.
- User validation testing was completed, demonstrating that the device confirms to the user needs and intended use.
- Packaging verification and shelf life testing was completed, supporting the labeled shelf life of the device.
- Physical properties testing has been provided by the material manufacturer.

Summary:

The uLab Systems Dental Aligner Kit has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the uLab Systems Dental Aligner is substantially equivalent to the cleared predicate device.