February 24, 2022

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

Re: K211510
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 27, 2022
Received: January 31, 2022

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 Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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)*
K211510

Device Name
uLab Systems Dental Aligner Kit

Indications for Use *(Describe)*
The uLab Systems Dental Aligner is indicated for the alignment of 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 – K211510

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

Applicant Information:

uLab Systems, Inc.
1820 Gateway Drive
Suite 300
San Mateo, CA 94404

Contact Person: Amir Abolfathi
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 Device:

Smylio Invisible Clear Aligners (Smylio, Inc.), K212660

Reference Device:

uLab Systems Dental Aligner Kit (uLab Systems, Inc.), K192596

Date Prepared:

February 22, 2022

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 customized by dental professionals using uLab

Systems technology. The aligners are made of aesthetic and medical grade materials. 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 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 primary 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 orthodontictreatment of malocclusions by way of continuous gentle forces.
- Both devices have the same principle of operation.
- Both devices are fabricated based on an orthodontic treatment plan designed from digital scans of the patient's teeth in an untreated state.
- For both devices, the treatment plan is approved by the prescribing physician prior to manufacturing.
- Both devices are made of thermoplastic.
- Treatment with both devices are monitored by the patient's dental health professional from placement of the first aligner through the delivery of the final aligner.

The only differences between the subject and predicate devices 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 materials as used in the reference device, whereas the predicate device materials are an unspecified thermoplastic.
- The indications for use for the subject device include the mode of action for correction of malocclusion: "by way of continuous gentle forces." The subject device does not include the words "permanent teeth" as compared to the reference device. However, this is in alignment with the Indications for Use for the primary predicate device.

Attribute	Subject Device uLab Systems Dental Aligner Kit (uLab Systems)	Primary Predicate Smylio Invisible Clear Aligners (Smylio, Inc.) K212660	Reference Device uLab Systems Dental Aligner Kit (uLab Systems) K192596
Indications for Use	The uLab Systems Dental Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.	The Smylio Invisible Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.
Device Description	A series of customized removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.	A series of customized removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.	A series of customized 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.	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	Standard dental software, including 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	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	Standard dental software, including 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

Attribute	Subject Device uLab Systems Dental Aligner Kit (uLab Systems)	Primary Predicate Smylio Invisible Clear Aligners (Smylio, Inc.) K212660	Reference Device uLab Systems Dental Aligner Kit (uLab Systems) K192596
	plan, the software converts the files to produce the series of 3D models used to produce thermoformed aligners.	produce the series of 3D models used to produce thermoformed aligners.	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	Zendura A (thin thermoformed polyurethane) or Zendura FLX (copolyester and polyurethane composite)
Features	Aligners made from different materials as prescribed by physician	Aligners made from different materials as prescribed by physician for daytime or nighttime use	Aligners made from different materials as prescribed by physician
OTC or Rx	Rx	Rx	Rx
Sterilization	No	No	No

Performance Data:

The performance testing remains unchanged from the company's own reference device submission, K192596. The performance testing for the subject device is being leveraged from the company's own reference device including: biocompatibility (ISO 10993-5, ISO 10993-10), design verification and process validation testing, user validation testing, packaging verification and shelf life testing, and physical properties testing by the material manufacturer.

Conclusion:

The uLab Systems Dental Aligner Kit has the similar Indications for Use as the predicate device and identical technological characteristics as the company's own reference device. Performance data demonstrates that any differences in technological characteristics between the primary predicate device and subject device do not raise different questions of safety or effectiveness or are supported by the reference predicate. Therefore, the uLab Systems Dental Aligner Kit is substantially equivalent to the cleared predicate devices.