June 23, 2020

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

Re: K200772
Trade/Device Name: ULab Systems uDesign Software
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: March 23, 2020
Received: March 25, 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)*

K200772

Device Name

uLab Systems uDesign Software

Indications for Use *(Describe)*

The uLab Systems uDesign is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, and of Indirect Bonding Transfer Media, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of uLab Systems uDesign requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

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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**FORM FDA 3881 (7/17)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

# 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.
1820 Gateway Drive
Suite 300
San Mateo, CA 94404

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

**Submission Correspondent:**

Sylvia Erickson
Principal, Sylvia Erickson Consulting

**Device Information:**

| | |
|---|---|
| Trade Name: | uLab Systems uDesign Software |
| Common Name: | Orthodontic Software |
| Classification Name: | Orthodontic Plastic Bracket |
| Classification Regulation: | 21CFR 872.5470 |
| Device Class: | II |
| Product Code: | PNN, LLZ |

**Primary Predicate:**

uLab Systems uDesign Software, K171295

**Reference Device:**

3Shape A/S Ortho System, K152086

**Date Prepared:**

June 23, 2020

**Device Description:**

The ULab Systems UDesign is orthodontic diagnosis and treatment simulation software for use by dental professionals. UDesign imports patient 3-D digital scans and allows the user to diagnose the orthodontic

treatment needs of the patient and rapidly develop a treatment plan. The output of the treatment plan may be downloaded as files in standard stereolithographic (STL) format for fabrication of dental casts, which may be used to fabricate sequential aligner trays or retainers, and of indirect bonding transfer trays.

**Indications for Use:**

The uLab Systems uDesign is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, and of Indirect Bonding Transfer Media, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of uLab Systems uDesign requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

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

| Substantial Equivalence Table | | | | |
|---|---|---|---|---|
| **Attribute** | **Subject Device**<br>Modified uLab Systems uDesign with IDB Software Module | **Primary Predicate**<br>uLab Systems uDesign (K171295) | Reference Device<br>3Shape A/S Ortho System (K152086) | **Differences** |
| **Intended Use** | | | | |
| **Product Code** | PNN, LLZ | PNN, LLZ | PNN, LLZ | None |
| **Common Name** | Orthodontic Software | Orthodontic Software | Orthodontic Software | None |
| **Classification Name** | Orthodontic Plastic Bracket | Orthodontic Plastic Bracket | Orthodontic Plastic Bracket | None |
| **Regulation Number** | 21 CFR 872.5470 | 21 CFR 872.5470 | 21 CFR 872.5470 | None |
| **Intended Use** | • Used by dental professionals in orthodontic treatment planning (before, during, after treatment)<br>• Management of patients and models<br>• Inspection, measurement and analysis of orthodontic models<br>• Treatment simulation<br>• Virtual appliance preparation (including dental casts), handling and export<br>• Provides digital file and device output | • Used by dental professionals in orthodontic treatment planning (before, during, after treatment)<br>• Management of patients and models<br>• Inspection, measurement and analysis of orthodontic models<br>• Treatment simulation<br>• Virtual dental casts preparation, handling and export<br>• Provides digital file output | • Used by dental professionals in orthodontic treatment planning (before, during, after treatment)<br>• Management of patients and models<br>• Inspection, measurement and analysis of orthodontic models<br>• Treatment simulation<br>• Virtual appliance preparation (including dental casts), handling and export<br>• Provides digital file and device output | All 3 devices output STL files for fabrication of dental casts.<br><br>The Subject Device and Reference Device both additionally output Indirect Bonding Transfer Media. |
| **Indications for Use** | The ULab Systems UDesign is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, | The ULab Systems UDesign is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed | 3Shape Ortho System is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, | The indications for use for the 3 devices are the same, with the exception of the virtual design options.<br><br>Compared to the Primary Predicate, the Subject Device additionally is |

| | | | | |
|---|---|---|---|---|
| | detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, **and of Indirect Bonding Transfer Media,** based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of ULab Systems UDesign requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software. | analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of ULab Systems UDesign requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software. | treatment simulation and virtual appliance design options (Custom Metal Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Ortho System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software. | used for design of Indirect Bonding Transfer Media.<br><br>The Subject Device virtual design options are a subset of the virtual design options for the Reference Device, which is additionally used for design of custom metal bands. |
| **Intended User** | Dental Professionals | Dental Professionals | Dental Professionals | None |
| **Intended Patient Population** | Patients with malocclusion | Patients with malocclusion | Not specified | The intended patient population for the subject and Primary Predicate is a subset of the intended patient population for the Reference Device, which is not defined. |

The subject and the predicate devices share the same intended use as software used by dental professionals in orthodontic treatment planning for management of patients and orthodontic models; inspection, measurement and analysis of the models; treatment simulation; preparation and export of a series of virtual dental casts.

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

- All are stand-alone software designed for use in management of 3D orthodontic models from patient scans;
- All may be used to design a series of dental casts;
- All apply digital imaging tools based on 3D orthodontic models for in orthodontic case archiving, diagnosis, treatment planning and CAD design;
- All provide virtual planning of orthodontic treatments simulating tooth movements;
- All support stereolithography (STL file format).

Whereas the primary predicate device designs only dental casts and the reference device designs custom metal bands and indirect bonding transfer trays in addition to dental casts, the subject device designs dental casts and indirect bonding transfer trays. The reference device additionally accepts inputs in multiple formats; the subject device only accepts STL file formats.

**Performance Data:**

Software and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005).

The testing includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

All test results met acceptance criteria, demonstrating the uLab Systems uDesign performs as intended, raises no new or different questions of risk and is substantially equivalent to the predicate device.

**Summary:**

The uLab Systems uDesign has the same intended use as the predicate devices. In addition, it has similar technological characteristics; performance data demonstrates that the device should perform as intended in the specified use conditions. Therefore, the uLab Systems uDesign is substantially equivalent to the cleared predicate devices.