3Shape A/S
Kristian Nielsen
Regulatory Affairs Specialist
Holmens Kanal 7
Copenhagen,1060 DK

October 17, 2010

Re: K180941
Trade/Device Name: Ortho System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: September 13, 2018
Received: September 13, 2018

Dear Kristian Nielsen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180941

Device Name
Ortho System 2017-1

Indications for Use *(Describe)*
Ortho System™ for dental retainers and dental cast for sequential aligners 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 appliance design options based on 3D models of the patient's dentition before the start of an orthodontic treatment.

The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as 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.

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510(K) SUMMARY K180941

K180941

Submitter Information

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Contact Person:	Kristian Worziger Nielsen Regulatory Affairs Specialist
Date Summary Prepared:	August 10, 2018

Device Identification

510(k) number:	K180941
Trade/proprietary Name:	Ortho System™
Regulation Number:	872.5470
Regulation Name:	Orthodontic Plastic Bracket
Classification:	Class II
Product Code:	PNN (Orthodontics Software)

Primary Predicate Device

The Ortho System™ intended for dental retainers and dental cast for sequential aligners (K180941), is based on the information and supporting documentation provided, and has the same intended use, scientific concept, performance specification and technical characteristics as the primary predicate device ULab Systems UDesign (K171295) from ULab Systems, Inc.

Both software devices are used by Dental Professionals in orthodontic treatment planning (before, during, after treatment) covering management of patients and models, inspection, 2D and 3D measurement and orthodontic analysis of models, 2D & 3D treatment simulation, as well as virtual appliance preparation, handling and export, and they are both providing CAM output for 3D printers and milling machines.

Specifically, the functionality included in the new, extended, indications for use for the proposed device to realize dental casts for sequential aligners by the use of digitally design and then produced by approved materials are identical for the two devices.
Therefore, the Ortho System™ (K180941) and the predicate (K171295) are found to be similar in their intended use, supported anatomic areas and the available relevant features and functionalities.

Reference devices

The proposed device has two reference devices K163677 (Ortho System™ for Dental Retainers) and K171634, which uses the functions and tools of Ortho System™ to produce different orthodontic dental appliances using either thermoforming on a produced cast or direct production. Both of these devices have the same fundamental technological characteristics as the primary predicate device, as they are consolidated in the single medical software.

Based on the information and supporting documentation provided, the reference devices do not alter the performance specification nor technical characteristics of the primary predicate device.

Indications for Use

Ortho System™ for dental retainers and dental cast for sequential aligners 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 appliance design options based on 3D models of the patient's dentition before the start of an orthodontic treatment.

The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

Device Description

3Shape's Ortho System™ for dental retainers and dental cast for sequential aligners is a software system used for the management of 3D scanned orthodontic models of the patients, orthodontic diagnosis by measuring, analysing, inspecting and visualize 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements, and design of orthodontic appliances based on 3D scanned orthodontic models.

The realization of the orthodontic appliances are done using appliance workflows templates which either supports

- (Retainers and dental casts for sequential aligners) Thermoforming FDA cleared or listed material on a dental cast. The cast is designed and produced by machines and materials included in the appliance workflow template
- (Retainers) Direct production using 3D printer or milling machines with FDA cleared or listed materials included in the appliance workflow template.

The Ortho System™ appliance workflow templates with approved machines is available through a dedicated download centre by the software.
The instruction for use contains instructions for configuration of additive printers.

The actual production of appliances/casts and any thermoforming is done by the user and is under their control and responsibility – only materials specified in the manual must be used to produce the final appliance.

The Ortho System™ has no patient contact being a software.

Materials for sequential aligner production

Materials to be used for production of sequential aligners are restricted to the FDA cleared material K062828.

Scientific Concept

The underlying scientific concept of the Ortho System™ is to apply digital imaging tools for orthodontic case archiving, diagnosis, treatment planning and CAD design of customized appliances.

It is possible to create a *virtual orthodontic setup* for a future planned position of the teeth, which can be exported and realized as appliances, see device description. For some appliance types, virtual positioning of brackets is possible with the use of encrypted libraries of the bracket geometry provided by the manufacturers and available through a dedicated download centre in the software.

The system supports the following types of digital data: DICOM, STL, JPG, BMP, PNG.

Summary of the technological characteristics

Ortho System™ is a software only device programmed in Delphi and has the following PC/laptop hardware requirements equivalent to the reference devices:

Item	Minimum Requirements Ortho System (K180941)	Minimum Requirements 3Shape Ortho System (K171634)
OS:	Windows 7, 8 or 10 64-bit	Windows 7, 8 or 10, 64-bit
RAM:	8 GB	8 GB
Monitor Resolution:	1280x800 or similar	1280x800 or similar
Video Card Memory:	1 GB	1 GB
Available HDD Space:	250 GB	250 GB
CPU:	Intel Core i5 or equivalent	Intel Core i5 or equivalent
Network:	Network Internet connection	Network Internet connection
Mouse:	With wheel button	With wheel button

The Ortho System™ Software has the same intended uses and technical characteristics as ULab Systems UDesign (K171295) from ULab Systems, Inc.:

Feature name	Ortho System™ K180941	Ulabs UDesign K171295
Management of 3D orthodontic models from patient scans	Yes	Yes

Design a series of dental casts	Yes	Yes
Digital imaging tools based on 3D orthodontic models for in orthodontic case archiving, diagnosis, treatment planning and CAD design	Yes	Yes
Virtual planning of orthodontic treatments simulating tooth movements	Yes	Yes
Stereolithography (STL file format)	Yes	Yes

Nonclinical Testing

Software, hardware, 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 on May 11, 2005).

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

All test results have been reviewed and approved, showing the Ortho System™ to be substantially equivalent to the reference devices.

Clinical Testing

Clinical testing is not a requirement and has not been performed.

Conclusion

Based on a comparison of intended use, indications, principle of operations, features and technical data, and the test results, the Ortho System™ for dental retainers and dental cast for sequential aligners is found to be as safe and as effective as the primary predicate device.
Intended use and performance is found to be substantially equivalent to the primary predicate device, ULab Systems UDesign (K171295) from ULab Systems, Inc.