



3Shape A/S
Antje Marquardsen
Director Regulatory Affairs
Holmens Kanal 7
Copenhagen, 1060 Dk

January 17, 2018

Re: K171634
Trade/Device Name: Ortho System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: November 21, 2017
Received: November 24, 2017

Dear Antje Marquardsen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 -S

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

Indications for Use

510(k) Number (if known)

K171634

Device Name

Ortho System™

Indications for Use (Describe)

The 3Shape Ortho System™ 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 (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 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 – Special 510(K) – K171634**Submitter Information**

Company Name: 3Shape A/S

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Contact Person: Antje Marquardsen
Director, Regulatory Affairs

Date Summary Prepared: January 16, 2018

Device Identification

510(k) number: K171634

Trade/proprietary Name: Ortho System™

Regulation Number: 872.5470

Regulation Name: Orthodontic Plastic Bracket

Classification: Class II

Product Code: PNN (Orthodontic Software)

Primary Predicate Device

The Ortho System™ intended for dental retainers has the same intended use, scientific concept, performance specification and technical characteristics as the primary predicate device 3Shape Ortho System™ (K152086) from 3Shape A/S.

Based on the information and supporting documentation provided, the Ortho System™ and the primary predicate device (K152086) have same intended use.

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 device output.

Additionally, the indirect bonding functionality of both systems is intended for use with commercially available brackets and wires.

The only modifications compared to the primary predicate device, besides look and feel of the user interface, are:

1. A workflow improvement to view present and ideal position of teeth at

- the same time (dual view) with the introduction of arch wire in Indirect Bonding.
2. The ScanIt Manager is used for all scanners instead of ScanIt Orthodontics and ScanIt Ortho Impression that both are retracted.

Therefore, the Ortho System™ and the predicate (K152086) are found to be similar in their intended use, supported anatomic areas and the majority of the available features and functionalities.

Reference Predicate devices

The Ortho System have two reference predicate devices K161884 and K163677, which uses the functions and tools of Ortho System™ to produce different orthodontic dental treatments than the primary predicate device. Both of these devices have the same fundamental scientific technology as the primary predicate device, as they are consolidated in the single medical software.

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

Indications for Use

Ortho System™ 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 (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 as to have received a dedicated training in the use of the software.

Device Description

3Shape's Ortho System™ 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, virtual placement of orthodontic brackets on the 3D models and design of orthodontic appliances based on 3D scanned orthodontic models, including transfer methods for indirect bonding of brackets. Output includes only Export Model (also called dental casts), Custom Metal Bands (also called metal bands), and Indirect Bonding Transfer Trays (also called orthodontic bracket placement trays). All devices are to be fabricated from FDA cleared materials by third party under the responsibility of the user.

The device has no patient contact.

Scientific Concept

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

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 center 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:

Item	Minimum Requirements Ortho System (K171634)	Minimum Requirements 3Shape Ortho System (K152086)
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 the 3Shape Ortho System™ (K152086) from 3Shape A/S:

Feature name	Ortho System™ (K171634)	<u>3Shape</u> Ortho System™ (K152086)
Supported anatomic areas	Maxilla	Maxilla
	Mandible	Mandible
Intended use		
Managing patient and case base data	Yes	Yes
Collection of study material	Yes	Yes

Alignment of study material	Yes	Yes
Measuring study material	Yes	Yes
Analyzing study material	Yes	Yes
Treatment simulation	Yes	Yes
Virtual appliance design	Yes	Yes
Supported PC formats	Windows	Windows
Managing patient and case base data		
Creating, editing, deleting and copying patient data	Yes	Yes
Creating, editing, deleting and copying case data	Yes	Yes
Feature name	Ortho System™ (K171634)	<u>3Shape</u> Ortho System™ (K152086)
Collection of study material		
Surface scan for intra-oral scanner	Yes	Yes
Surface scan from STL file	Yes	Yes
CT image data	DICOM	DICOM
2D overlay	PNG, JPG, BMP	PNG, JPG, BMP
Alignment of study material		
Aligning surface scan and CT image	Yes	Yes
Aligning cephalometric images	Yes	Yes
Alignment of 2D overlays (e.g. ideal arch)	Yes	Yes
Ability to check/adjust DICOM visibility	Yes	Yes
DICOM scan segmentation	No	No
Measuring study material		
2D measurement toolbox	Yes	Yes
3D measurement toolbox	Yes	Yes
Analyzing study material		
Arch shape	Yes	Yes

Wire length	Yes	Yes
Tooth width	Yes	Yes
Bolton	Yes	Yes
Space analysis	Yes	Yes
Overjet/overbite	Yes	Yes
Occlusion map	Yes	Yes
Treatment simulation		
2D & 3D simulation	Yes	Yes

Feature name	Ortho System™ (K171634)	3Shape Ortho System™ (K152086)
Virtual appliance design		
Orthodontic appliance search	Yes	Yes
Orthodontic appliance virtual preparation	Yes	Yes
Orthodontic appliance design	Yes	Yes
Orthodontic appliance export	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 primary predicate device.

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™ 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.