November 27, 2019

3Shape A/S
Shreyosi Chakraborty
Regulatory Affairs Specialist
Holmens Kanal 7
DK-1060 Copenhagen K

Re: K191911
Trade/Device Name: 3Shape Splint Design
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: PNN
Dated: September 10, 2019
Received: September 13, 2019

Dear Shreyosi Chakraborty:

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 Nandkumar, Ph.D.
Acting 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)*
K191911

Device Name
3Shape Splint Design

Indications for Use *(Describe)*
3Shape Splint Design for splints and mouthguards/nightguards is intended for use as a medical front-end device providing tools for systematic inspection, detailed analysis, treatment simulation and virtual appliance design based on 3D models of the patient's dentition before the start of an orthodontic treatment.

The use of Splint Design software 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY K191911

Submitter Information

Company Name:	3Shape A/S
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Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
Contact Person:	Shreyosi Chakraborty Regulatory Affairs Specialist
Date Summary Prepared:	September 3, 2019

Device Identification

510(k) number:	K191911
Trade/proprietary Name:	3Shape Splint Design
Regulation Number:	872.5470
Classification:	Class 2
Product Code:	PNN (Orthodontic Software)

Primary Predicate Device

The Splint design software for splints and mouthguards/nightguards (K191911), based on the information and supporting documentation provided, and has the same intended use, scientific concept and technical characteristics as the primary predicate device 3Shape Ortho System™ - Splint (K161884) also manufactured by 3Shape A/S.

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

Specifically, the functionality included in the new, the proposed device to realize splints and mouthguards/nightguards using of digital design manufactured by approved materials are identical for the two devices.
Therefore, the Splint Design software (K191911) and the predicate (K161884) are found to be similar in their intended use, supported anatomic areas and the available relevant features and functionalities.

Indications for Use

3Shape Splint Design for splints and mouthguards/nightguards is intended for use as a medical front-end device providing tools for systematic inspection, detailed

analysis, treatment simulation and virtual appliance design based on 3D models of the patient's dentition before the start of an orthodontic treatment.

The use of Splint Design software 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

The Splint design software for splints and mouthguards/nightguards is a software system used for the virtual planning of orthodontic treatments by simulating jaw movements, and design of orthodontic appliances based on 3D scanned orthodontic models.

The realization of the above-mentioned orthodontic appliances is done using splint workflow which supports

- Direct production using 3D printer or milling machines with FDA cleared or listed materials included in the splint workflow.

The actual production of appliances is done by the user and it is under their control and responsibility.

3Shape Splint Design has no patient contact being a software only device.

Scientific Concept

The underlying scientific concept of the Splint Design software is to apply digital imaging tools for orthodontic treatment planning and CAD design of customized appliances.

The system supports the following types of digital data: dcm and STL

Summary of the technological characteristics

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

Item	Minimum Requirements Splint Design (K19XXXX)	Minimum Requirements 3Shape Ortho System™ (K161884)
OS:	Windows 7, 8 or 10 64-bit	Windows 7 or 8, 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 Splint Design software has the same intended uses and technical characteristics as the Ortho System™ software (K161884) also manufactured by 3Shape A/S:

Feature ID & Name	**Splint Design K191911**	**Ortho System™ K161884**	**Applicable for Splint and Mouthguard/Nightguard Treatment Simulation**
Supported anatomic areas	Maxilla	Maxilla	Yes
	Mandible	Mandible	Yes
Intended use			
1. Managing patient and case base data	No	Yes	No
2. Collection of study material	Yes	Yes	Yes
3. Alignment of study material	No	Yes	No
4. Measuring study material	Yes	Yes	Yes
5. Analyzing study material	Yes	Yes	Yes
6. Treatment simulation	Yes	Yes	Yes
7. Virtual appliance design	Yes	Yes	Yes
8. Supported PC formats	Windows	Windows	
Managing patient and case base data			
1.1 Creating, editing, deleting and copying patient data	No	Yes	No
1.2 Creating, editing, deleting and copying case data	No	Yes	No
Collection of study material			
2.1 Surface scan for intra-oral scanner	Yes	Yes	Yes
2.2 Surface scan from STL file	Yes	Yes	Yes
2.3 CT image data	No	DICOM	No
2.4 2D overlay	No (PNG, JPG, BMP)	PNG, JPG, BMP	No
Alignment of study material			

3.1 Aligning surface scan and CT image	No	Yes	No
3.2 Aligning cephalometric images	No	Yes	No
3.3 Alignment of 2D overlays (e.g. ideal arch)	No	Yes	No
3.4 Ability to check/adjust DICOM visibility	No	Yes	No
3.5 DICOM scan segmentation	No	No	No
Measuring study material			
4.1 2D measurement toolbox	Yes	Yes	Yes
4.2 3D measurement toolbox	No	Yes	No
Analyzing study material			
5.1 Arch shape	No	Yes	No
5.2 Wire length	No	Yes	No
5.3 Tooth width	No	Yes	No
5.4 Bolton	No	Yes	No
5.5 Space analysis	No	Yes	No
5.6 Overjet/overbite	No	Yes	No
5.7 Occlusion map	Yes	Yes	Yes
Treatment simulation			
6.1 2D & 3D simulation	No	Yes	No
6.2 Virtual articulator	Yes	Yes	Yes
Virtual appliance design			
7.1 Orthodontic appliance search	No	Yes	No
7.2 Orthodontic appliance virtual preparation	No	Yes	No
7.3 Orthodontic appliance design	Yes	Yes	Yes
7.4 Orthodontic appliance export	Yes	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 Splint Design software for splints and mouthguards/nightguards is found to be as safe and as effective as the primary predicate device. Therefore, intended use and performance are found to be substantially equivalent to those of the primary predicate device.