DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2016

3Shape A/S
Ms. Hanne Nielsen
Regulatory Affairs Manager
Holmens Kanal 7
DK-1060 Copenhagen
DENMARK

Re: K152086
Trade/Device Name: 3Shape Ortho System ™
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: PNN, LLZ
Dated: March 15, 2016
Received: March 18, 2016

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152086

Device Name
3Shape Ortho System™

Indications for Use *(Describe)*
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 – Traditional 510(K)

Submitter Information

A Company Name:	3Shape A/S
B Company Address:	Holmens Kanal 7 DK-1060 Copenhagen K
C Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
D Contact Person:	Hanne Nielsen Regulatory Affairs Manager
E Date Summary Prepared:	April 25, 2016

Device Identification

A Trade/proprietary Name:	3Shape Ortho System™
B Common Name:	Orthodontic Plastic Brackets
C Device Classification Name:	Orthodontic Treatment Planning and Diagnosis Software
C Regulation Number:	872.5470
C Classification:	Class II
D Product Code:	PNN (Orthodontic Software); LLZ

Predicate Device

The 3Shape Ortho System™ Software has the same intended uses and technical characteristics as primary predicate OrthoCAD iQ (K082207) from Cadent Inc. and reference predicate Dolphin Imaging from Patterson Dental Supply (K110430) as listed in "Volume 005, Comparison to Predicate Devices, Table 1: Predicates".

Based on the information and supporting documentation provided, the 3Shape Ortho System™ Software and the primary predicate (OrthoCAD) 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. Therefore, the 3Shape Ortho System™ Software and the primary predicate (OrthoCAD) are found to be similar in their intended use, supported anatomic areas and the majority of the available features and functionalities.

Indications for Use

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.

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, analyzing, 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.

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
OS:	Windows 7 or 8 64-bit
RAM:	8 GB
Monitor Resolution:	1280x800 or similar
Video Card Memory:	1 GB GeForce

Available HDD Space:	250 GB
CPU:	IntelCore i5 or equivalent
Network:	Network Internet connection
Mouse:	With the wheel button

The Ortho System™ Software has the same intended uses and technical characteristics as OrthoCAD iQ (K082207) from Cadent Inc. and Dolphin Imaging from Patterson Dental Supply (K110430):

Feature name	**3Shape Ortho System™**	**Primary predicate Cadent Inc. OrthoCAD iQ (K082207)**	**Reference predicate Patterson Dolphin Imaging (K110430)**
Supported anatomic areas	Maxilla	Maxilla	Maxilla
	Mandible	Mandible	Mandible
Intended use			
Managing patient and case base data	Yes	Yes	Yes
Collection of study material	Yes	Yes	Yes
Alignment of study material	Yes	Yes	Yes
Measuring study material	Yes	Yes	Yes
Analyzing study material	Yes	Yes	Yes
Treatment simulation	Yes	Yes	Yes
Virtual appliance design	Yes	Yes	Yes
Supported PC formats	Windows	Windows	Windows
Managing patient and case base data			
Creating, editing, deleting and copying patient data	Yes	Yes	Yes
Creating, editing, deleting and copying case data	Yes	Yes	Yes

Feature name	**3Shape Ortho System™**	**Primary predicate Cadent Inc. OrthoCAD iQ (K082207)**	**Reference predicate Patterson Dolphin Imaging (K110430)**
Collection of study material			
Surface scan for intra-oral scanner	Yes	Yes	Yes
Surface scan from STL file	Yes	Yes	Yes
CT image data	DICOM	No	DICOM
2D overlay	PNG, JPG, BMP	JPEG	PNG, JPG, BMP
Alignment of study material			
Aligning surface scan and CT image	Yes	No	Yes
Aligning cephalometric images	Yes	No	Yes
Alignment of 2D overlays (e.g. ideal arch)	Yes	No	Yes
Ability to check/adjust DICOM visibility	Yes	No	Yes
DICOM scan segmentation	No	No	Yes
Measuring study material			
2D measurement toolbox	Yes	Yes	Yes
3D measurement toolbox	Yes	Yes	Yes
Analyzing study material			
Arch shape	Yes	Yes	Yes
Wire length	Yes	Yes	Yes
Tooth width	Yes	Yes	Yes
Bolton	Yes	Yes	Yes
Space analysis	Yes	Yes	Yes
Overjet/overbite	Yes	Yes	Yes
Occlusion map	Yes	Yes	Yes
Treatment simulation			
2D & 3D simulation	Yes	Yes	Yes

Feature name	**3Shape** **Ortho System™**	**Primary predicate Cadent Inc. OrthoCAD iQ (K082207)**	**Reference predicate Patterson Dolphin Imaging (K110430)**
Virtual appliance design			
Orthodontic appliance search	Yes	Yes	Yes
Orthodontic appliance virtual preparation	Yes	Yes	Yes
Orthodontic appliance design	Yes	No	Yes
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 predicates.

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 effective as the predicate devices. Intended use and performance is found to be substantially equivalent to the Predicate Devices.