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

September 6, 2016

3Shape A/S
Hanne Nielsen
Regulatory Affairs Manager
Holmens Kanal 7
Copenhagen, 1060
DENMARK

Re: K151455
Trade/Device Name: 3Shape Abutment Designer™ Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: January 8, 2016
Received: January 11, 2016

Dear Hanne 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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,


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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K151455

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY – Traditional 510(K)

## Submitter Information

| | |
|---|---|
| A Company Name: | 3Shape A/S |
| B Company Address: | Holmens Kanal 7<br>DK-1060 Copenhagen K |
| C Company Phone:<br>Company Fax: | +45 7027 2620<br>+45 7027 2621 |
| D Contact Person: | Hanne Nielsen<br>Regulatory Affairs Manager |
| E Date Summary Prepared: | June 28, 2016 |

## Device Identification

| | |
|---|---|
| A Trade/proprietary Name: | 3Shape Abutment Designer™ Software |
| B Common Name: | Abutment design software for dental laboratory |
| C Device Classification Name: | Endosseous Dental Implant Abutment |
| C Regulation Number: | 872.3630 |
| C Classification: | Class II |
| D Product Code: | PNP |

## Predicate Device

Sirona Dental CAD/CAM System (K100152).

## Intended Use

The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental

implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

## Device Description

The 3Shape Abutment Designer™ Software receives scan data containing topographical characteristics of real teeth, dental impressions, or stone models. The software provides the user with the ability to create matching endosseous dental implant abutments using computer aided design.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by manufacturers that hold an implant abutment 510(k) or are milling per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment. The 3Shape Abutment Designer Software output is restricted in the U.S. to be manufactured by a holder of an implant abutment 510(k) or milled per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment.

The 3Shape Abutment Designer™ Software can be run on properly configured "off-the-shelf" PC hardware running Microsoft® Windows and using a standard keyboard and mouse.

The 3Shape Abutment Designer™ Software requires the loading of implant libraries, which includes information such as implant type, maximum and minimum dimensional parameters for abutments, etc., created by separate abutment manufacturers and cleared by the FDA. In the US, the Implant Libraries are obtained via a 3Shape server after demonstration to 3Shape of the FDA clearance of the Implant Library.

## Summary of the technological characteristics

The 3Shape Abutment Designer™ is a software only device programmed in the Delphi programming language and has the following PC/laptop requirements and other technological characteristics as compared to the predicate device:

| Item | Submission Device Minimum Requirements | Submission Device Recommended | Predicate Device |
|---|---|---|---|
| OS | Windows 7 32-bit Professional* | Windows 7 64-bit Professional | Windows Vista 32- bit |
| RAM | 4GB | 8GB (16GB) | 6GB |
| Video Card | 512MB DirectX 10 (1GB DirectX 10) | 1GB DirectX 11 (2GB DirectX 11) | 512 MB DirectX 10<br><br>NVIDIA Quadro |
| Available HDD Space | 250GB | 500GB (1TB) | 500GB |
| CPU | Intel Core i5 or equivalent | Intel Core i7 or equivalent | Intel Core i7 |
| Monitor resolution | 1440 x 900 pixels | 1920 x 1080 pixels | Unknown |
| 3D Mouse | None | 3DConnexion SpaceMouse™ | Unknown |
| Network | Internet connection | | Unknown |
| Ports | USB 2.0 port for 3Shape desktop scanner | | Serial Port PCI card for inEOS scanner |
| Mouse | Mouse with wheel button support | | Unknown |

| | | |
|---|---|---|
| Indications for Use | The 3Shape Abutment Designer Software is intended as an aid in the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device. | The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unti cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and asesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the CAMlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), and Straumann SynOcta (K061176). |
| Software Output | Digital encrypted or non-encrypted proprietary or .STL file including only the patient-specific abutment component for one-piece, two-piece, or hybrid abutment designs. The digital output does not include the abutment-to-implant connection interface. | .STL file of the ceramic mesostrucutre sent to Sirona Dental CAD/CAM System milling unit |
| Physical - Output | N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company | Two-piece Tibase abutment – pre-milled titanium base combined with ceramic mesostructure designed in Sirona CAD/CAM software. |
| Milling Location | Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment | Local milling of the ceramic abutment component. |

The predicate Sirona device includes in the marketing clearance the two-piece TiBase Abutments (titanium bases and ceramic blocks) as a physical output as well as a validated milling unit and directions for assembly of the final dental abutment. The 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient. The 3Shape Abutment Designer Software instead provides only the digital design as an accessory to the physical dental abutment systems cleared by other manufacturers. The differences between the Indications for Use

Statement of the submission device and the predicate are related to the lack of physical output from the submission device and reliance on previous or subsequent FDA clearance of the physical abutment by a separate manufacturer. However, the difference does not change the intended use of the device.

## 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) as well as the FDA Guidance Document "Off-The-Shelf Software Use in Medical Devices (Issued on September 9, 1999).

Prior to release, verification and validation testing of the 3Shape Abutment Designer™ Software has been completed using the approved acceptance criteria: Each user need has its own validation acceptance criteria; each specification has its own verification acceptance criteria; bug verification consists in ensuring issue is not reproducible; issues reported by beta partners must be reviewed and handled appropriately; beta partners must report functionality to be an improvement over previous version.

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

## Conclusion

Based on a comparison of intended use, principle of operations, features and technical data, and the verification/validation test results, the 3Shape Abutment Designer™ Software is found to be substantially equivalent with the Predicate Device.