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

October 31, 2014

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

Re: K141570
Trade/Device Name: Implant Studio
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 10, 2014
Received: October 14, 2014

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 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,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K141570

Device Name
Implant Studio

Indications for Use *(Describe)*
Implant Studio™ is indicated for use as a medical front-end software that can be used by medically trained professionals for the purpose of visualizing gray value images. It is intended for use as a pre-operative planning software for the placement of dental implant(s) based on imported CT image data, optionally aligned to an optical 3D surface scan. Virtual Crowns can be used for optimized implant positioning under the prosthetic aspect. The digital three dimensional model of a surgical guide for a guided surgery can be designed based on the approved implant position. This 3D data can be exported to manufacture a separate physical product.
Indications of the dental implants do not change with guided surgery compared to conventional surgery.
Use of the software requires that the user has the necessary medical training in implantology and surgical dentistry.

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 Medical 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:	May 28, 2014

Device Identification

A Trade/proprietary Name:	Implant Studio™
B Common Name:	Implant Planning and Surgical Guide
C Device Classification Name:	Picture archiving and communications system
C Regulation Number:	892.2050
C Classification:	Class II
D Product Code:	LLZ

Predicate Device

The 3Shape Implant Studio™ Software has the same intended uses and major functions as Dentsply Simplant 2011 (K110300) and Straumann AG coDiagnostix (K130724). Testing demonstrates the implementation functions as intended, and differences between the Device and the predicates do not raise additional concerns with the Device's safety and effectiveness.

Indications for Use/Intended Use

Implant Studio™ is indicated for use as medical front-end software that can be used by medically trained professionals for the purpose of visualizing gray value images. It is intended for use as pre-operative planning software for the placement of dental implant(s) based on imported CT image data, optionally aligned to an optical 3D surface scan. Virtual Crowns can be used for optimized implant positioning under the prosthetic aspect. The digital three dimensional model of a surgical guide for a

guided surgery can be designed based on the approved implant position. This 3D data can be exported to manufacture a separate physical product.

Indications of the dental implants do not change with guided surgery compared to conventional surgery.

Use of the software requires that the user has the necessary medical training in implantology and surgical dentistry.

Device Description

Implant Studio™ is a software only device used to pre-operatively plan the placement of a dental implant and to visualize a patient's CT image, optionally aligned to an optical 3D surface data. Virtual crown(s) can be used to guide the planning under the final prosthetic aspect. The surgical guide data can be designed then exported to an external system for manufacturing.

The device has no patient contact.

Scientific Concept

The underlying scientific concept is the visualization of an imported CT image from DICOM data to pre-operatively analyze and plan the placement of dental implant(s) in the maxilla and/or mandible region by taking the prosthetic and clinical requirements into consideration. Optionally, the CT image can be aligned to optical 3D surface scan data. The implant and sleeve library files are provided via encrypted library files which are generated by 3Shape and approved by the corresponding original manufactures. CAD designed virtual crown(s) can be used to assist during the planning phase. Moreover, the use of CAD design technology allows the design of a surgical guide, which can be exported to a 3rd party manufacturing device. The guide can be used for aiding the placement of the implant(s) to the intended position(s). PDF reports are generated to document the planning information and to provide an overview of the required surgical components.

Summary of the technological characteristics

Implant Studio™ is a software only device programmed in C# and has the following PC/laptop hardware requirements:

Item	Minimum Requirements
OS:	Windows 7 or 8 64-bit
RAM:	8GB or better
Monitor Resolution:	1280x800 or higher
Video Card Memory:	1GB GeForce or better
Available HDD Space:	250GB
CPU:	IntelCore i5 or higher

Network:	Network Internet connection
Mouse:	With the wheel button

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).

Prior to release, verification and validation testing of the Implant Studio 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.

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 Implant Studio to be substantially equivalent in safety and effectiveness to the predicate.

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 Implant Studio is found to be substantially equivalent in safety and effectiveness to the predicate. Intended use and performance is found to be substantially equivalent to the Predicate Devices.