DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

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

3Shape Medical A/S   December 4, 2015
℅ Ms. Hanne Nielsen
Regulatory Affairs Manager
Holmens Kanal 7
DK-1060 Copenhagen
DENMARK

Re: K152078
     Trade/Device Name: Implant Studio™ 2015
     Regulation Number: 21 CFR 892.2050
     Regulation Name: Picture archiving and communications system
     Regulatory Class: II
     Product Code: LLZ
     Dated: November 5, 2015
     Received: November 9, 2015

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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
  and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K152078

Device Name

Implant Studio™ 2015

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.

510(K) SUMMARY – Special 510(K)

Submitter Information

A Company Name: 3Shape Medical A/S

B Company Address: Holmens Kanal 7
                                  DK-1060 Copenhagen K

C Company Phone: +45 7027 2620
   Company Fax: +45 7027 2621

D Contact Person: Hanne Nielsen
                                  Regulatory Affairs Manager

E Date Summary Prepared: July 23, 2015

Device Identification

A Trade/proprietary Name: Implant Studio™ 2015-1

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™ 2015-1 Software still has the same intended uses and major functions as Dentsply Simplant 2011 (K110300) and Straumann AG coDiagnostix (K130724).

Furthermore the 510(k) is submitted to modify a legally marketed device, the indications for use of the proposed device are unchanged and fundamental scientific technology of the proposed device is unchanged from the previous legally marketed device (Implant Studio 2014-1 – K141570).

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.

Device Comparison

3Shape Implant Studio™ 2015-1 covered in this submission is based on the same technology platform as the previously cleared 3Shape Implant Studio™ 2014-1.

The main difference between these two devices is the introduction is a dedicated workflow for edentulous treatment and the related software features and functionalities to plan for this treatment concept. The following table compares all newly added features and functionalities between these two devices and the selected predicate devices:

Feature name	3Shape Implant Studio™ 2015	3Shape Implant Studio™ 2014	Straumann coDiagnostiX	Dentsply Simplant 2011
510(k) Number		K141570	K130724	K110300
Segmentation of Denture CT scan	Yes	No	Yes	Yes
Alignment of CT scan data via radiopaque markers	Yes	No	Yes	Yes
Option to manually align two scan data set	Yes	No	Yes	Yes
Support for anchor pins	Yes	No	Yes	Yes
Gingiva supported surgical guide design possible	Yes	No	Yes	Yes

* Picture archiving and communications system, 21CFR892.2050

The added support for edentulous treatment and subsequent design of gingiva supported guides in the 2015 version of Implant Studio™ are identical in the intended use but also available features and functionalities compared to the predicated devices.

The difference between Implant Studio™ 2015-1 and Implant Studio™ 2014-1 software as well the predicate devices do not raise additional concerns regarding its safety and effectiveness.

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 scan data can be aligned to optical 3D surface scan data or to a segmented CT scan of a denture. 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™ 2015-1 is a software only device programmed in C# and has the following recommended PC/ laptop hardware requirements:

Item	Recommended
OS:	Windows 7 or 8 64-bit
RAM:	16GB or better
Monitor Resolution:	1920x1200 or higher
Video Card Memory:	2GB GeForce or better
Available HDD Space:	500GB
CPU:	IntelCore i7 or higher
Network:	Network Internet connection
Mouse:	With the wheel button

Note! For the edentulous workflow, 4GB video memory is recommended.

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 2015-1 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 2015-1 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.