3Shape Medical A/S
% Mr. Rafael Aguila
Official Correspondent
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
LUDLUM FL 33155

September 9, 2020

Re: K202256
Trade/Device Name: 3Shape Implant Studio
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 7, 2020
Received: August 10, 2020

Dear Mr. Aguila:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K202256

Device Name

3Shape Implant Studio

Indications for Use *(Describe)*

3Shape Implant Studio is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. This software reads imaging information output from medical scanners such as CT and optical scanners. It allows pre-operative simulation and evaluation of patient anatomy and dental implant placement.

Surgical guides and the planned implant position can be exported as 3D models and the guides can be manufactured using said 3D models when used as input to 3D manufacturing systems.

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 K202256

Submitter Information

Company Name:	3Shape Medical A/S
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Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
Contact Person:	Jenny Axel Regulatory Affairs Specialist
Date Summary Prepared:	September 4, 2020

Device Identification

510(k) number:	K202256
Trade/proprietary Name:	3Shape Implant Studio
Regulation Number:	892.2050
Classification:	Class 2
Product Code:	LLZ

Primary Predicate Device

The 3Shape Implant Studio® for implant planning and surgical guides (K202256), based on the information and supporting documentation provided, has the same indications for use, scientific concept and technical characteristics as the predicate device Straumann AG coDiagnostix
(K130724) and the reference device 3Shape Implant Studio™ 2015-1 (K152078) also manufactured by 3Shape Medical A/S.

Both, subject and predicate devices, are computer aided design software used by dental professionals trained in implantology for implant planning and the design of surgical guides after import of scan imaging data. The designed 3D models and surgical reports are exported from both devices. Therefore, the 3Shape Implant Studio® software (K202256) and the predicate device (K130724) are found to be similar in their indications for use, supported anatomic areas and the available relevant features and functionalities.

Indications for Use

3Shape Implant Studio® is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. This software reads imaging information output from medical scanners such as CT and optical scanners. It allows pre-operative simulation and evaluation of patient anatomy and dental implant placement.

Surgical guides and the planned implant position can be exported as 3D models and the guides can be manufactured using said 3D models when used as input to 3D manufacturing systems.

Device Description

3Shape Implant Studio® is a stand-alone software device used to pre-operatively plan the placement of a dental implant based on the visualization of a patient's CT image, optionally aligned to an optical 3D surface scan. A virtual surgical guide can be designed and then exported to an external system for manufacturing.

The device has no patient contact being a software only device.

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 available to the practitioner via encrypted library files, which are reviewed and approved by the original manufactures of the components. 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 steps and components.

Summary of the technological characteristics

3Shape Implant Studio® is a software only device programmed in C# and has the following PC/laptop hardware requirements equivalent to the reference device:

Item	Minimum Requirements 3Shape Implant Studio® (K202256)	Minimum Requirements Straumann AG coDiagnostix (K130724)	Minimum Requirements Implant Studio™ 2015-1 (K152078)
OS:	Windows 7, 8 or 10 64-bit	Windows 7, Sp or Vista	Windows 7 or 8 64-bit
RAM:	16 GB	2 GB	16 GB or better
Monitor Resolution:	1920x1080	1024x768 pixels	1920x1200 pixels or higher
Video Card Memory:	2GB NVIDIA (GeForce or Quadro), DirectX 10/11. Maxwell or newer architecture recommended	-	2GB GeForce or better

Available HDD Space:	500 GB	1 GB free, plus 50 MB per plan	500 GB
CPU:	Intel Core i7 or equivalent	Intel Core or AMD Athlon 64 X2	Intel Core i7 or higher
Network:	Network Internet connection	-	Netweork Internet connection
Mouse:	With the wheel button	-	Mouse with wheel button support

3Shape Implant Studio® has the same indications for use and technical characteristics as the predicate device, Straumann AG coDiagnostix (K130724).

The following table compares all newly added features and functionalities between the subject, predicate and reference devices:

Feature name	**3Shape Implant Studio®**	**Straumann AG coDiagnostix**	**Implant Studio™ 2015-1**
510(k) Number	K202256	K130724	K152078
Segmentation of Denture CT scan	Yes	Yes	Yes
Alignment of CT scan data via radiopaque markers	Yes	Yes	Yes
Option to manually align two scan data set	Yes	Yes	Yes
Support for anchor pins	Yes	Yes	Yes
Gingiva supported surgical guide design possible	Yes	Yes	Yes
Bone supported surgical guide design possible	Yes	Yes	No

* Picture archiving and communications system, 21 CFR 892.2050

The added feature for design of bone supported surgical guides with identified and implemented risk mitigations in 3Shape Implant Studio® (K202256) is identical in indications for use and the available features and functionalities compared to the predicate 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).

The development of the subject software also utilized the following FDA guidances:

- Technical Considerations for Additive Manufactured Medical Devices;
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Prior to release, verification and validation testing of the 3Shape Implant Studio® has been completed using 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 encountered by users during the summative evaluation have been 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 3Shape Implant Studio® to be substantially equivalent in safety and effectiveness to the primary predicate device.

The 3Shape Implant Studio® complies with the following standards:

- IEC 62304
- ISO 13485
- ISO 14971
- IEC 62366
- IEC 80001-2-2
- NEMA PS 3.1 - 3.20

Clinical Testing

Clinical testing is not a requirement and has not been performed.

Conclusion

Based on a comparison of intended use, indications for use, scientific concept, features, technical data, and test results, the 3Shape Implant Studio® is found to be as safe and effective as the primary predicate device. Therefore, 3Shape Implant Studio® is found to be substantially equivalent with the primary predicate device.