October 7, 2020

3Shape A/S
Jenny Axel
Regulatory Affairs Specialist
Holmens Kanal 7
Copenhagen 1060
DENMARK

Re: K200100
Trade/Device Name: Abutment Design
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: July 13, 2020
Received: July 15, 2020

Dear Jenny Axel:

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 Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K200100

Device Name
Abutment Design

Indications for Use *(Describe)*
Abutment Design is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. Abutment Design 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 resulting 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.

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510(K) SUMMARY K200100

Submitter Information

Company Name:	3Shape 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:	October 7, 2020

Device Identification

510(k) number:	K200100
Trade/proprietary Name:	Abutment Design
Regulation Number:	872.3630
Classification:	Class 2
Product Code:	PNP
Regulation Name:	Endosseous dental implant abutment

Primary Predicate Device

The primary predicate device is 3Shape Abutment Designer™ (K151455) manufactured by 3Shape A/S.

The Abutment Design software for abutments (K200100), based on the information and supporting documentation provided, has the same intended use, scientific concept, and technical characteristics as the primary predicate device (K151455).

Both software devices are used by dental professionals for the design of endosseous dental implant abutments, and the devices ensure only FDA cleared abutment systems can be used.

Therefore, the Abutment Design software (K200100) and the predicate (K151455) are found to be similar in their intended use, supported anatomic areas and the available relevant features and functionalities.

Indications for Use

Abutment Design is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. Abutment Design 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 resulting abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Device Description

The Abutment Design 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 Abutment Design is restricted to be used with 510(k) cleared abutment systems, and the design output from Abutment Design (the patient specific part of the abutment) must be manufactured according to the instruction of the selected abutment system.

The Abutment Design software includes design parameters from the 510(k) cleared abutment systems such as implant type, maximum and minimum dimensions (e.g., abutment post height, gingival height, angulation, gingival margin diameter, etc.). The design parameters, provided by abutment system manufacturers, for an abutment system are available via a 3Shape server when documentation of the 510(k) clearance of said implant system is presented to 3Shape.

Abutment Design has no patient contact being a software only device.

Scientific Concept

The underlying scientific concept of the Abutment Design software is to apply digital imaging tools for computer aided design, CAD, of abutments.

The system supports the following types of digital data: DCM and STL

Summary of the technological characteristics

Abutment Design™ is a software only device programmed in C# and Delphi and has the following PC/laptop hardware requirements equivalent to the reference device:

Item	Minimum Requirements Abutment Design (K200100)	Minimum Requirements 3Shape Abutment Designer™ (K151455)
OS:	Windows 7, 8, 8.1 or 10 (64-bit)	Windows 7 32-bit Professional*
RAM:	8 GB	4 GB
Monitor Resolution:	1920x1080 pixels	1440x900 pixels
Video Card Memory:	1GB DirectX 11	512MB DirectX 10 (1GB DirectX 10)
Available HDD Space:	500 GB (1TB if used as a standalone system or a server with the order folder)	250 GB

CPU:	Intel Core i7 or equivalent	Intel Core i5 or equivalent
Network:	Network Internet connection	Internet connection
USB ports:	USB 2.0 port for 3Shape desktop scanner	USB 2.0 port for 3Shape desktop scanner
Mouse:	With the wheel button support	Mouse with wheel button support
3D Mouse:	(Optional) 3DConnexion SpaceMouse™ Pro	(Recommended)3DConnexion SpaceMouse™

The Abutment Design software has the same intended uses and technical characteristics as the Abutment Designer™ software (K151455) also manufactured by 3Shape A/S:

Feature name	**Abutment Design K200100**	**Abutment Designer ™ K151455**	**Identical to Predicate**
1. Graphical UI	Yes	Yes	Yes
2. Windows OS platform	Yes	Yes	Yes
3. Uses standard PC hardware	Yes	Yes	Yes
4. Digitally imports topography of teeth by 3D Scan	Yes	Yes	Yes
5. Uses 3D CAD design tools	Yes	Yes	Yes
6. Patient specific abutment design	Yes	Yes	Yes
7. Implant Bar design	No	Yes	No, outside indications for use
8. Export to remote milling machine by internet	Yes	Yes	No, the subject device workflow requires instructed user actions
9. Network Protocol	Internet/TCP-IP	Internet/TCP-IP	Yes
10. Intended users	Dental practitioners and dental technicians	Dental practitioners and dental technicians	Yes
11. Output type	Digital encrypted or non-encrypted	Digital encrypted or non-encrypted	Yes

	proprietary or .STL file only of the patient-specific abutment component, not including the abutment-to-implant connection interface. If encryption is active or not will solely be determined by the 510(k) clearance of the abutment system.	proprietary or .STL file only of the patient-specific abutment component, not including the abutment-to-implant connection interface. If encryption is active or not will solely be determined by the 510(k) clearance of the abutment system.	
12. Device submission includes pre-manufactured prosthetics*	No	No	Yes

* Endosseous dental implant abutments as per 21CFR872.3630

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.

The cybersecurity analysis was performed in accordance with the FDA Guidance Document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", issued on October 02, 2014.

All test results have been reviewed and approved, showing the Abutment Design™ to be substantially equivalent to the primary predicate device.

Clinical Testing

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

Conclusion

Based on a comparison of intended use, indications, scientific concept, features and technical data, and test results, the Abutment Design software is found to be as safe and effective as the primary predicate device. Therefore, Abutment Design is found to be substantially equivalent with the primary predicate device.