exocad GmbH
% Mr. Stefan Walter
Quality Manager
37, Julius-Reiber-Str.
Darmstadt, Hessen 64293
GERMANY

August 6, 2019

Re: K183458
Trade/Device Name: exoplan 2.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 25, 2019
Received: July 3, 2019

Dear Mr. Walter:

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)*
K183458

Device Name

exoplan 2.3

Indications for Use *(Describe)*

exoplan is a medical software, intended to support the pre-operative planning of dental implants using the visualization of the implant placement within images of the patient's anatomy. The process is based on CT/CBCT data sets originating from other medical devices, and can be supported by optical scan(s) of the patient's anatomy as well as a virtual prosthetic proposal.

exoplan allows the design of surgical guides to support the placement of endosseous dental implants in guided surgery. The design of surgical guides is based on 3D surface data representing the preoperative situation and approved implant positions. The software exports the planning and design results as geometrical data and a digital 3D model of the surgical guide to support the manufacture of a separate physical product. exoplan does not extend or change indications of dental implants. Usage of a surgical guide designed with the software does not change the necessary due diligence required compared to conventional (non-guided) surgery.

The software is intended to be used only by dental professionals with sufficient medical training in dental implantology and surgical dentistry in office environments suitable for reading diagnostic dental DICOM data sets. exoplan shall not be used for any purpose other than planning dental implant placement or design of surgical guides.

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, Traditional 510(k) K183458

Submitter Information

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Establishment Registration number: 3011521456

Date prepared: 2019-08-05

Manufacturing Facility

Same as submitter.

Device Information

Trade/proprietary Name:	exoplan 2.3
Common Name/Usual name:	Dental Implant Planning and tooth retained Surgical Guide design software application
Device Classification Name:	Picture archiving and communications system
Regulation Number:	892.2050
Classification:	Class II
Classification Product Code:	LLZ

Predicate Device

exoplan has been compared to the following predicate legally marketed device:

510(k) Number:	K152078
Predicate device:	Implant Studio™ 2015
Manufacturer:	3Shape A/S, Holmens Kanal 7, DK-1060 Copenhagen K

Intended Use

exoplan is a medical software, intended to support the pre-operative planning of dental implants using the visualization of the implant placement within images of the patient's anatomy. The process is based on CT/CBCT data sets originating from other medical devices, and can be supported by optical scan(s) of the patient's anatomy as well as a virtual prosthetic proposal.

exoplan allows the design of surgical guides to support the placement of endosseous dental implants in guided surgery. The design of surgical guides is based on 3D surface data representing the preoperative situation and approved implant positions. The software exports the planning and design results as geometrical data and a digital 3D model of the surgical guide to support the manufacture of a separate physical product. exoplan does not extend or change indications of dental implants. Usage of a surgical guide designed with the software does not change the necessary due diligence required compared to conventional (non-guided) surgery.

The software is intended to be used only by dental professionals with sufficient medical training in dental implantology and surgical dentistry in office environments suitable for reading diagnostic dental DICOM data sets. exoplan shall not be used for any purpose other than planning dental implant placement or design of surgical guides.

Device Description & Summary of Technical Characteristics

exoplan is a standalone software application for the purpose of pre-operative implant planning and design of surgical guides to support the surgical intervention.

The software application runs on "off-the-shelf" PC hardware with current Microsoft Windows operating system (7, 8.1,10, 64 Bit), off-the shell GPU card and otherwise standard peripheral components.

The device allows importing 3D CT data and dental scan data (e.g. scans from teeth, dental impression, or stone models) from compatible intraoral or desktop scanners. While the planning of implant position is mainly based on the information of the CT data, the design of a surgical guide is based on the STL data of the dental scan. Both modalities are registered to a common coordinate system to ensure that the implant positions defined by a user can be used for design of a surgical guide.

exoplan uses so called Implant Libraries that contain information provided by the original manufacturer of a respective physical implant, reconstruction parts on top of the implant, such as stock abutments or titanium bases. Libraries also contain drilling sleeves and tools of surgical kit items, such as drills and drill handles. The libraries are digitally signed and by that any modification of a library content or the referred library parts or files will be detected by exoplan reported to the user and documented in an Implant Planning Report or Surgical Protocol document.

exoplan has no contact with the patient.

Note! In the US, the physical surgical guide for endosseous dental implant placement is a medical device to be manufactured at an FDA registered and listed manufacturing location.

Non-clinical Testing

Software verification and validation is performed in accordance with the applicable guidance document ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005). Prior to release of exoplan the verification and validation of the device has been completed. Each user requirement and each product requirement derived thereof has an own acceptance criteria. Detected anomalies are evaluated, resolved or where appropriate in case of a minor issue described in the release notes. The verification and validation includes the verification and where appropriate validation of the risk mitigation measure as defined by the risk analysis. Feedback of software testers and feedback from validation is regarded in the device as appropriate.

Summary of tests and accuracy results

This section lists several tests that verify important accuracies in various working steps in the exoplan workflow as can be achieved with the exoplan software. The selected tests verify accuracies of critical items in the whole workflow of exoplan:

- 3D CT data visualization accuracy
- Density threshold accuracy
- Measurement accuracy
- CT data to optical scan data alignment accuracy
- Implant placement accuracy
- Collision detection accuracy
- Sleeve placement accuracy
- Rotation marker accuracy
- Accuracy of surgical guide bottom compared to jaw scan
- Accuracy of merged output compared to individual parts (mount, surgical guide top)
- Accuracy of merged surgical guide fit on surgical guide bottom

The following table provides an overview on the tests above and the achieved accuracy.

#	Tested Accuracy	Result
3D CT data visualization accuracy		
1.	Visualization of iso-surface of CT data accuracy	accuracy of visualization of 3D CT data is 10% of the maximum voxel size (voxel size: 1mm, therefore accuracy 0.1mm)
Density threshold accuracy		
2.	Density threshold accuracy in 3D CT data	visualization accuracy for a perfectly selected threshold is 10% of maximum voxel size.
Measurement accuracy		
3.	Accuracy of distance measurement in 3D CT data, rendering modes “iso-surface”, “solid”	In general, dimensional measurement has an accuracy of 0.01mm. Clicking on DICOM object in iso-surface or solid rendering mode has an additional limitation of 10% of the voxel size
4.	Accuracy of distance measurement in STL meshes	Achievable accuracy of dimensional measurements in mesh data: 0.01mm
5.	Accuracy of angle measurement	achievable accuracy of measurement of angles in mesh data: 0.5°
CT data to optical scan data alignment accuracy		
6.	CT Data alignment accuracy, 3 Point Alignment & Best Fit Alignment	3 Point Alignment, achievable accuracy: 1mm Best Fit Alignment, in general the achievable accuracy depends on the resolution of the input data. For this data set the achievable accuracy is 0.2mm
Implant placement accuracy		
7.	Implant placement accuracy	Achievable accuracy of 0.3 mm relative to CT data
Collision detection accuracy		
8.	Collision detection accuracy, visual	Collisions are detected: Implant/implant, marked nerve/implant, collision object mesh/implant
9.	Collision detection accuracy	Collision detection accuracy: 0.01mm
Sleeve placement accuracy		
10.	Drill Sleeve placement accuracy,	Accuracy of placing a sleeve along the implant axis: 0.01mm
Rotation marker accuracy		
11.	Drill Sleeve rotation accuracy,	Achievable repetitious accuracy of 1°
Accuracy of surgical guide bottom compared to jaw scan		
12.	Accuracy of Surgical Guide bottom,	Accuracy of the surgical guide bottom to the optical scan data plus the user defined offset is 0.1mm in smooth areas without undercuts
Accuracy of merged output compared to individual parts (mount, surgical guide top)		
13.	Accuracy of merged Surgical Guide parts	Accuracy of the surgical guide individual parts to the surface of the merged parts is 0.01mm in smooth areas
Accuracy of merged surgical guide fit on surgical guide bottom		
14.	Accuracy of merged Surgical Guide bottom,	Accuracy of the surgical guide bottom to the surface of the merged bottom is 0.01mm in smooth areas

Clinical

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

Comparative information on Predicate Device

exoplan has been compared to the following legally marketed predicate device:

510(k) Number: K152078
Predicate device: Implant Studio™ 2015

The following tables provides a comparison of the predicate device with exoplan.

Comparable Criteria	Predicate device	Device under evaluation	Eval.
Trade/ proprietary Name, 510(k) #:	K152078, Implant Studio™ 2015	exoplan	---
Device Classification Name:	Picture archiving and communications system	Picture archiving and communications system	Identical
Regulation Number:	892.2050	892.2050	Identical
Classification:	Class II	Class II	Identical
Product Code:	LLZ	LLZ	Identical
Prescription/ over the counter use	Prescription use	Prescription use	Identical
Intended use / indications / description	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.	exoplan is a medical software, intended to support the pre-operative planning of dental implants using the visualization of the implant placement within images of the patient's anatomy. The process is based on CT/CBCT data sets originating from other medical devices, and can be supported by optical scan(s) of the patient's anatomy as well as a virtual prosthetic proposal. exoplan allows the design of surgical guides to support the placement of endosseous dental implants in guided surgery. The design of surgical guides is based on 3D surface data representing the preoperative situation and approved implant positions. The software exports the planning and design results as geometrical data and a digital 3D model of the surgical guide to support the manufacture of a separate physical product. exoplan does not extend or change indications of dental implants. Usage of a surgical guide designed with the software does not change the necessary due diligence required compared to conventional (non-guided) surgery. The software is intended to be used only by dental professionals with sufficient medical training in dental implantology and surgical dentistry in office environments suitable for reading diagnostic dental DICOM data sets. exoplan shall not be used for any purpose other than planning dental implant placement or design of surgical guides.	Equivalent
Users	necessary medical training in implantology and surgical dentistry	dental professionals with sufficient medical training in dental implantology and surgical dentistry	Equivalent
Input data	CT image data and optical surface scan	CT image data and optical surface scan	Identical
Registration / Alignment	Registration / Alignment of CT image data and optical surface scan	Registration / Alignment of CT image data and optical surface scan	Identical
Output data	surgical report, drill protocol is provided, STL file with designed guide for manufacturing	Implant planning report, surgical protocol, STL file with designed guide for manufacturing	Equivalent
Handling of risk structures	Definition of mandibular nerve canal, collision detection with implant during implant planning	Definition of mandibular nerve canal, collision detection with implant during implant planning	Equivalent
Surgical guide manufacturing	Transfer to a manufacturing site.	Transfer to a manufacturing site.	Identical
Hardware	Any compatible of-the shelf PC, GPU, monitor and network connection	Any compatible off-the-shelf PC with a dedicated GPU, monitor and network connection	Identical
GUI OS	Windows ® 7, 8.1, 10 ; 32 and 64 bit Operating System	Windows ® 7, 8.1, 10 ; 64 bit Operating System	Equivalent

Based on the comparison of intended use, principles of operation, features, characteristics, technical data and results of the verification and validation, we conclude that exoplan is substantially equivalent to the predicate device 3Shape, Implant Studio™ 2015, and therefore safe to use as intended.