May 3, 2022

exocad GmbH
% Tobias Turba
Quality Engineer
37, Julius-Reiber-Str.
Darmstadt, Hesse 64293
GERMANY

Re: K213302
Trade/Device Name: exoplan
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 29, 2022
Received: March 31, 2022

Dear Tobias Turba:

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 and Part 809; 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213302

Device Name
exoplan

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. Alternatively, instead of optical surface data a second CBCT/CT dataset can be used. 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.

510(k) Summary, Traditional 510(k)

Submitter Information

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Germany

Contact Person: Tobias Turba, Quality Engineer
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Establishment Registration number: 3011521456

Date prepared: 2021-09-29

Manufacturing Facility

Same as submitter.

Device Information

Trade/proprietary Name:	exoplan
Common Name/Usual name:	Dental Implant Planning and tooth/gingiva supported Surgical Guide design software
Device Classification Name:	Medical image management and processing 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:	K183458
Device name:	exoplan 2.3
Manufacturer:	exocad GmbH, Julius-Reiber-Str. 37, 64293 Darmstadt

Reference Device

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

510(k) Number:	K202256
Device name:	Implant Studio™
Manufacturer:	3Shape A/S, Holmens Kanal 7, DK-1060 Copenhagen

Indications for 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.

Alternatively, instead of optical surface data a second CBCT/CT dataset can be used.

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 Microsoft Windows 10 operating system (64 Bit), off-the shell GPU card and otherwise standard peripheral components.

The device allows importing 3D CT and optical scans (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 optical 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 component libraries, which contain information (e.g., physical dimensions, compatibility, etc.) provided by the original manufacturer of a component, and cover all components that can be used during treatment and necessary to consider during planning, e.g. implants, drills and drill sleeves. The libraries are digitally signed. This ensures that any modification of the content of a library will be detected by exoplan. The issue is then reported to the user and documented in the Implant Planning Report or the Surgical Protocol.

exoplan has no contact with the patient.

Non-Clinical Performance 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 derived product requirement has an own acceptance criteria. Detected anomalies are evaluated, resolved or where appropriate (e.g. in case of a minor issue) described in the release notes. The verification and validation include 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. Furthermore, accuracy tests were performed to verify that the planning results are as accurate as defined.

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 devices:

Predicate Device: exoplan 2.3 (K183458)

Reference Device: Implant Studio (K202256)

Comparable Criteria	Device under evaluation	Predicate device	Reference device	Eval.
Trade/ proprietary Name, 510(k) #:	exoplan	exoplan (K183458)	K202256, Implant Studio™	---
Reason for comparison	---	Primary software features and functionality. Predecessor of the exoplan version that is subject to this submission.	Features that are not available in the predicate device: - Edentulous case planning - Virtual tooth extraction	---
Device Classification Name:	Medical image management and processing system	Medical image management and processing system	Medical image management and processing system	same
Regulation Number:	892.2050	892.2050	892.2050	same
Classification:	Class II	Class II	Class II	same
Product Code:	LLZ	LLZ	LLZ	same
Prescription/ over the counter use	Prescription use	Prescription use	Prescription use	same
indications for 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. Alternatively, instead of optical surface data a second CBCT/CT dataset can be used. 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	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	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.	Highly Similar to the predicate Similar to the reference

	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.	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.		
Users	dental professionals with sufficient medical training in dental implantology and surgical dentistry	dental professionals with sufficient medical training in dental implantology and surgical dentistry	dental professionals who have appropriate knowledge in dental implantology and surgical dentistry	Same as predicate Highly similar to reference
Input data	CT image data and optical surface scan	CT image data and optical surface scan	CT image data and optical surface scan	same
Registration / Alignment of CR image data and optical surface scan	Yes	Yes	Yes	same
Output data	Implant planning report, surgical protocol, STL file with designed guide for manufacturing	Implant planning report, surgical protocol, STL file with designed guide for manufacturing	surgical report, drill protocol is provided, STL file with designed guide for manufacturing	same
Avoidance of Risk Areas (anatomical markers)	Mandibular nerve canal and sinus cavity	Mandibular nerve	Mandibular nerve	same technology, additional locations, validated through performance testing.
Ability to create guides for edentulous patients	Yes	No	Yes	same as reference
Virtual Tooth Extractor	Yes	No	Yes	Same as reference
Surgical guide manufacturing	Transfer to a manufacturing site.	Transfer to a manufacturing site.	Transfer to a manufacturing site.	same
Hardware	Any compatible off-the-shelf PC with a dedicated GPU, monitor and network connection	Any compatible off-the-shelf PC with a dedicated GPU, monitor and network connection	Any compatible of-the shelf PC, GPU, monitor and network connection	same
GUI OS	Windows ® 10; 64-bit Operating System	Windows ® 7, 8.1, 10 ; 64-bit Operating System	Windows ® 7, 8.1, 10 ; 32 and 64-bit Operating System	Highly similar– removed older, not supported OS for security

Overall, the subject and predicate as well as reference devices are the same or highly similar, with any differences mitigated through non-clinical performance testing and software validation, supporting a finding of substantial equivalence. New features are similar to those included in the reference device and the results of verification and validation ensure that the new device is as safe and as effective.