July 21, 2021

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

Re: K193352
Trade/Device Name: AbutmentCAD
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: June 13, 2021
Received: June 21, 2021

Dear Stefan 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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K193352

Device Name

AbutmentCAD

Indications for Use *(Describe)*

The AbutmentCAD module is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. AbutmentCAD is a software device intended to be used by trained professionals in dental practices or dental laboratories for the design of patient specific implant borne prosthetics such as one-piece abutments, two-piece/hybrid abutments, single or multi-unit screw-retained restorations. The design result 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.

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K193352
510(k) Summary

Submitter Information

exocad GmbH
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Germany
Contact Person: Stefan Walter, Quality Manager
Phone: +49-6151-629489-0

Establishment Registration number: 3011521456

Date prepared: 2021-07-21

Manufacturing Facility

Same as submitter.

Device Information

Trade/proprietary Name:	AbutmentCAD
Device Classification Name:	Dental Abutment Design Software for Dental Laboratory
Regulation Number:	872.3630
Classification:	Class II
Classification Product Code:	PNP

Predicate Device

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

510(k) Number:	K151455
Predicate device:	3Shape Abutment Designer
Manufacturer:	3Shape A/S, Holmens Kanal 7, DK-1060 Copenhagen K

Indications for Use

The AbutmentCAD module is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. AbutmentCAD is a software device intended to be used by trained professionals in dental practices or dental laboratories for the design of patient specific implant borne prosthetics such as one-piece abutments, two-piece/hybrid abutments, single or multi-unit screw-retained restorations. The design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Device Description & Summary of Technical Characteristics

AbutmentCAD is a software application for the purpose of designing patient-specific implant-based dental restorations, such as one-piece abutments, two-piece/hybrid abutments and single or multi-unit screw retained restorations. The AbutmentCAD software can be used with basic dental CAD systems such as exocad's ChairsideCAD. AbutmentCAD is used solely for the design of the patient-specific components of abutments and screw retained crowns and bridges.

The software application runs on "off-the-shelf" PC hardware with current Microsoft Windows operating system and standard peripheral components.

Design - Abutments

A restoration is designed based on the imported scan and the geometry information of objects in integrated implant libraries based on data of original implant manufacturers. These libraries contain data of connection geometries to implants and so called "design limitations" (also referred to as "design constraints" in other devices) in order to adhere to specific instructions of implant manufacturers of 510(k) cleared implants/abutments. For more details see next section.

The respective connection geometry cannot be changed in the design process. The usage of these libraries allows to design high precision, implant-based restorations for the following design options:

- Abutments, one-piece, two-piece/hybrid
- Bridges, screw retained (multi-unit crown)
- Crowns, screw retained
- Bars, screw retained

During the design of one of the above reconstructions, design limitations (e.g. angulation, height, etc.) stored in the Implant Libraries are verified so that items with design parameters beyond the defined limitations cannot be created with the AbutmentCAD software application. These limitations correspond to the specific instructions of the holder of an implant abutment 510(k).

The final design geometry along with information on the required material is transferred to a compatible milling system for manufacturing. Furthermore, with the information of a selected target milling machine for manufacturing of the part under design, additional information of specific capabilities of the machine are adhered to by AbutmentCAD directly at the stage of design to ensure that the part can be manufactured.

Manufacturing (not in the scope of the device under evaluation)

Restorations designed with AbutmentCAD may only be manufactured by holders of an implant abutment 510(k) or milled according to the specific instructions provided by the holder of a 510(k)-clearance for a patient-specific implant abutment.

Implant Libraries

AbutmentCAD uses so called abutment libraries that are based on detailed information, sizes, catalogue numbers, 3D meshes and information about design limitations (see below) of implants. All information is provided by the original manufacturer of a respective physical part and is integrated by exocad into a library. Implant libraries may contain, e.g. implants, a titanium bases and similar related parts.

AbutmentCAD loads the library parts during the design process. The connection geometry defined by the implant manufacturer cannot be modified at any time. The implant libraries allow to define so called design limitations such as maximum height or maximum angulation for the design of an abutment.

With the information of design limitations of the parts (e.g. the angulation or maximum height) contained in the implant libraries it is possible to control the design process and ensure that the design results conform to implant specific instructions of the implant manufacturer.

The libraries are digitally signed and by that any modification of a library content or the referred library parts or files is detected by AbutmentCAD and it is not possible to use the library.

Information contained in a library is:

- Data of interface parts, such as titanium bases, compatible to a specific implant, and interface geometry to the tooth reconstruction
- Data not used for the design, which serves merely for graphical representation during the design process (e.g. screw threads, implant analogs, pre-mill holders, and other meta information)
- Data defining the minimum thickness geometry as a lower limit to the design of implant-based restorations.
- Scan abutment data that allows recognition of the implant position within optical scan data
- Data of design limitations, as required by holder of an implant abutment 510(k), for implant-based tooth reconstructions, such as maximum and minimum dimensional parameters.
- Connection geometry and screw channel geometry, permitting a design of reconstruction with an interface, e.g. titanium base and direct-to-implant tooth reconstruction (e.g. single piece abutments/screw-retained crowns and bridges).

Design Limitations

The following design limitations are adhered to for the design of abutments:

- minimum wall thickness
- minimum and maximum height of the emergence profile
- minimum and maximum diameter of the emergence profile
- minimum and maximum height of the entire abutment
- minimum and maximum height of the abutment above the emergence profile
- minimum and maximum angulation of the abutment above the emergence profile in relation to the implant axis
- minimum and maximum angulation of the screw channel in relation to the axis of the abutment above the emergence profile
- minimum and maximum angulation of the screw channel in relation to the implant axis
- size limitation of the abutment due to the size of the pre-milled abutment blank
- restriction to specific tooth numbers (e.g. narrow implants are typically intended to be used for anterior teeth)

The following design limitations are adhered to for the design of screw retained bridges:

- overall length of a bridge
- length of a bridge arc between two implants
- length of a bridge extension
- length of a single unit implant-based bridge with bridge extension
- size requirements for the manufacturing of the bridge (size of the intended blank or stock material versus size of the bridge under design)

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 AbutmentCAD the verification and validation of the device has been completed. Each user requirement and each product requirement derived thereof has an own acceptance criteria.

A cybersecurity analysis was performed in accordance with the FDA Guidance Document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, issued on 2014-10-02. exocad monitors vulnerabilities of the products and components during lifetime and analyses them in a post-market-cybersecurity process that involves also risk management.

Detected anomalies are evaluated and either resolved or in case of a minor issue described in the release notes. The testing includes a validation with end-users of the product. Feedback of software testers and feedback from validation is regarded in the device as appropriate.

The described approach for testing also includes testing of cybersecurity requirements determined in the cybersecurity analysis.

During software verification we ensure that the design limitations are correctly triggered with an accuracy of 0.01mm for dimensional constraints and an accuracy of 0.5° for angular constraints. For verification realistic and artificial data and a 3rd party tools are used to proof the correctness of our software with respect of the design limitations.

In order to generate an abutment design library, exocad developed a software tool which is part of, and used in conjunction with AbutmentCAD. It is made available to the holder of an abutment 510(k) to support the creation abutment libraries which include specific design parameters of abutments. Use of this tool is mandatory for creating abutment libraries and ensures abutment design parameters are enforced through the design process. The software tool and its output have been validated as part of this premarket notification.

Comparative information on Predicate Device

Abutment CAD has been compared to the following predicate legally marketed device:

510(k) Number: K151455
Predicate device: 3Shape Abutment Designer

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

Comparable Criteria	Predicate device	Device under evaluation	Evaluation
Trade/ proprietary Name, 510(k) #:	3Shape Abutment Designer, K151455	AbutmentCAD 2.3	---
Device Classification:	Dental Abutment Design Software For Dental Laboratory	Dental Abutment Design Software For Dental Laboratory	Substantially equivalent
Regulation Number:	872.3630	872.3630	Substantially equivalent
Classification:	Class II	Class II	Substantially equivalent
Product Code:	PNP	PNP	Substantially equivalent
Prescription/ over the counter use	Prescription use	Prescription use	Substantially equivalent
Indications for Use	The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software 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 single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	The AbutmentCAD module is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. AbutmentCAD is a software device intended to be used by trained professionals in dental practices or dental laboratories for the design of patient specific implant borne prosthetics such as one-piece abutments, two-piece/hybrid abutments, single or multi-unit screw-retained restorations. The design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	Substantially equivalent
– used as	The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae.	The AbutmentCAD module is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae.	Substantially equivalent
– used by	"… intended for use by a dental practitioner or dental laboratory staff …"	"… intended to be used by trained professionals in dental practices or dental laboratories …"	Substantially equivalent
– used for	"… for designing the patient specific component of a two-piece, one-piece or hybrid dental implant abutment …"	"… for the design of patient specific implant borne prosthetics such as one-piece abutments, two-piece/hybrid abutments, single or multi-unit screw-retained restorations …"	Substantially equivalent
– result used by	"… design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device."	"… design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device."	Substantially equivalent
Input data	scan data containing topographical characteristics of real teeth, dental impressions, or stone models	scan data containing topographical characteristics of real teeth, dental impressions, or stone models	Substantially equivalent
Design options	endosseous dental implant abutments; as per specific instructions of the implant manufacturer	endosseous dental implant abutments; specific instructions of the implant manufacturer are adhered to during the design process	Substantially equivalent
Libraries	FDA clearance of the Implant Library.	FDA clearance of the Implant Library, validation by abutment 510(k) holder, cannot be modified by end-user.	Substantially equivalent
Output data	Digital encrypted or non-encrypted proprietary or .STL file including only the patient-specific abutment component for one-piece, two-piece, or hybrid abutment designs.	Digital encrypted or non-encrypted proprietary or .STL file including only the patient-specific abutment component for one-piece, two-piece, or hybrid abutment designs. Encryption status of the library will be determined solely by the 510(k)	Substantially equivalent

		clearance of the abutment system.	
Physical output	N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company	N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company	Substantially equivalent
Milling location	Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment	Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment	Substantially equivalent
Hardware	Compatible of-the-shelf PC	Any compatible of-the shelf PC, Monitor and network connection	Substantially equivalent
GUI OS	Windows 7 32-bit or 64-bit Professional	Windows ® 7, 8.1, 10; 64-bit Operating System	Substantially equivalent, Up-to-date OS used

AbutmentCAD has been compared to a legally marketed predicate device (3Shape Abutment Designer Software, K151455) as documented above. The conclusion is that, based on the comparison of intended use and various characteristics, AbutmentCAD is substantially equivalent to the predicate device.