Zirkonzahn SRL
% Ms. Sandra Leitner
Regulatory Affairs
Via An der Ahr 7
Gais, BZ 39030
ITALY

July 20, 2021

Re: K203765
Trade/Device Name: ZIRKONZAHN.Implant-Planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 23, 2021
Received: April 26, 2021

Dear Ms. Leitner:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203765

Device Name
ZIRKONZAHN.Implant-Planner

Indications for Use *(Describe)*
ZIRKONZAHN.Implant-Planner is an implant planning and surgery planning software. The software imports and reads DICOM files from CT/CBCT scanners. The patient data is then transformed into 3D volume and different multi-planar 2D images for diagnosis and further implant and surgery guide planning with precise step by step instructions. The software is a stand-alone product that is not connected to any other medical device. Neither automatic diagnosis nor automatic disease detection is performed. The software is intended for use by dental professionals only and requires appropriate training for its use and knowledge in the practice of implantology.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 05
510(k) Summary

K203765

510(k) SUMMARY

APPLICANT

ZIRKONZAHN SRL
Via An der Ahr 7
Gais, ITALY 39030
Phone: +39 0474 066 660
Fax: +39 0474 066 661
E-mail: info@zirkonzahn.com

CONTACT PERSON

Sandra Leitner
Regulatory Affairs
ZIRKONZAHN SRL
Via An der Ahr 7
Gais, ITALY 39030
Phone: +39 0474 066 784
Fax: +39 0474 066 661
E-mail: sandra.leitner@zirkonzahn.com

Date Summary Prepared: June 30, 2021

DEVICE IDENTIFICATION

Trade/Proprietary Name:	ZIRKONZAHN.Implant-Planner
Generic/Common Name:	Diagnostic imaging software for implant planning
Regulation Number:	892.2050
Regulation Description:	Medical Image Management and Processing System
Class:	II
Product Code:	LLZ

LEGALLY MARKED PREDICATE DEVICE

Trade name:	3DIEMME RealGUIDE
510(k) holder:	3DIEMME Srl
510(k) number:	K173041

INDICATIONS FOR USE

ZIRKONZAHN.Implant-Planner is an implant planning and surgery planning software. The software imports and reads DICOM files from CT/CBCT scanners. The patient data is then transformed into 3D volume and different multi-planar 2D images for diagnosis and further implant and surgery guide planning with precise step by step instructions. The software is a stand-alone product that is not connected to any other medical device. Neither automatic diagnosis nor automatic disease detection is performed. The software is intended for use by dental professionals only and requires appropriate training for its use and knowledge in the practice of implantology.

DEVICE DESCRIPTION

ZIRKONZAHN.Implant-Planner is a fully-featured 3D imaging standalone application for implant planning and surgical guide design. ZIRKONZAHN.Implant-Planner supports all the common 3D medical imaging functionalities used by professionals to support their diagnosis. It includes various volume and surface rendering, masking and sculpting, MPR, 2D and 3D measurement and analysis tools. The software is provided in 2 versions and 2 modules: the first version is a full version (called "ZIRKONZAHN.Implant-Planner") that covers all applications of the indications for use, the second version is a basic/limited version (called "ZIRKONZAHN.Implant-Planner Practice") only for implant planning. The first module is a CAD/CAM STL Converter that converts DICOM data into STL files for further processing. The second one is the CAD/CAM Z-Tray for designing individual impression trays.

Software	Item No	Nomenclature	Description
ZIRKONZAHN. Implant-Planner	SY1600	ZIRKONZAHN.Implant-Planner	All applications of the indications for use.
	SY1620	ZIRKONZAHN.Implant-Planner Practice	Version only for dental implant planning without surgical guide design.
	SY1610	CAD/CAM STL Converter	Converts DICOM volume data into 3D geometry (STL files) for further processing using other CAD software.
	SY1630	CAD/CAM Z-Tray	For manufacturing individual impression trays.

Table 1: Versions and additional modules description

As there is at least one medical function and at least one non-medical function ZIRKONZAHN.Implant-Planner is considered as multiple function device with the following structure:

Function	Device Function	Other Function	Item No
ZIRKONZAHN.Implant-Planner	X		SY1600
ZIRKONZAHN.Implant-Planner Practice	X		SY1620
CAD/CAM STL Converter		X	SY1610
CAD/CAM Z-Tray		X	SY1630

Table 2: Multiple Function Device Structure

NON-CLINICAL TESTS

Software verification and validation is performed in accordance with the procedures described in this submission and in accordance with the applicable FDA guidelines. Code review, unit, integration and system testing were conducted to establish the functionality and reliability characteristics of the subject device. Software validation confirms that the particular requirements implemented through software are consistently fulfilled. Implemented controls such as collision detection related to device hazards identified in the risk management procedures are validated to establish the safety of the device. Bench tests demonstrate the accuracy of critical items in the whole workflow of the device. The tests performed on the single items report satisfying results that back up the accurate performance of the new device for its achieved outputs when used as intended. The accuracy of data elaboration with its relative outcomes will ensure a safety placement of the implants in the clinical use and a positive impact on the overall healthcare situation.

CLINICAL TESTS

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

SUBSTANTIAL EQUIVALENCE

Devices	**ZIRKONZAHN.Implant-Planner**	**3DIEMME RealGUIDE**	**Comparison**
Company	**Zirkonzahn Srl**	**3DIEMME Srl**	
Product Code	LLZ	LLZ	Same
Regulation Number	892.2050	892.2050	Same
Indication for use	ZIRKONZAHN.Implant-Planner is an implant planning and surgery planning software. The software imports and reads DICOM files from CT/CBCT scanners. The patient data is then transformed into 3D volume and different multi-planar 2D images for diagnosis and further implant and surgery guide planning with precise step by step instructions. The software is a stand-alone product that is not connected to any other medical device. Neither automatic diagnosis nor automatic disease detection is performed. The software is intended for use by dental professionals only and requires appropriate training for its use and knowledge in the practice of implantology.	1. Support to the diagnosis for trained professionals. The input DICOM files acquired by a CT/CBCT scanner are not modified in any way but they are showed to the doctor through the classical imaging and volume rendering techniques. It is a stand-alone product. No information of the patient is modified, all the parameters used for the image processing are read from the DICOM file itself. Neither automatic diagnosis is made, nor automatic disease detection is performed. This software is not connected to any medical instrumentation and it doesn't control any medical or energy supplying device. The user imports DICOM data coming from any CT/CBCT imaging device and the software enables him to view the Patient exam in different multi-planar 2D images and easily reconstruct the 3D volume for an immediate visualization of bone structures and surrounding tissues. 2. Virtual oral and maxillofacial surgery planning. Doctors can plan virtual implants and surgeries on 2D/3D reconstructions and export the projects in open or proprietary format for further processing. The user can choose different implant models (for example dental implants models) from a library provided by the Manufacturers and simulate the positioning in the	Similar

		Patient reconstructed volume (this operation is called "virtual plan") 3. Dental/maxillofacial surgical guides and prosthetic modelling. The virtual plan is used to design a surgical guide that is used by the doctor to drive the surgery drills according to the planned implants direction and depth. This surgical guide can be manufactured by any 3D printer working from STL files. The user can also design the patient prosthesis (typically a denture) with the surface and volume free-form tools implemented in the software. The result is exported in STL format for 3D printing or CAD/CAM technologies. Mobile version: The RealGUIDE software APP is intended for the following uses: Projects visualization and editing. The input PROJECT files, pre-processed with the RealGUIDE desktop version, are used by trained professionals to evaluate the implants projects, edit them and share them with other colleagues through the cloud, as well as for a more effective Patient treatment communication. The RealGUIDE APP version is NOT INTENDED for managing a 3D diagnosis starting from DICOM images, due to the mobile devices screen resolution limitations. For this reason, the APP is not reading directly the DICOM files but only pre-processed project files, exported through the cloud by the RealGUIDE desktop version.	
System Requirements	PC Installation - Processor: Intel I5 or I7	PC Installation - Processor: Intel I5 or I7	Similar:

	- RAM: minimum 4 GB, 8 GB are suggested - Hard disk: 300 – 500 GB - Required Hard Disk Space: approx. 900 MB - Graphic Card: Nvidia Geforce. For higher performance Nvidia GTX or QUADRO - Screen Resolution: 1920 x 1080 - OS: Windows 7 (64 bit), Windows 8 (64 bit), Windows 10 (64 bit)	- RAM: minimum 4 GB, for big datasets 8 GB are suggested - Hard disk: 300 – 500 GB (for Patients storage) - Graphics card: Nvidia Geforce line (€150-200 price range). For higher performances Nvidia GTX o QUADRO line - Screen resolution: 1920 x 1080 for optimal visualization - OS: Windows 7 (64 bit), Windows 8 (64 bit), Windows 10 - For professional use we suggest the Dell XPS 15 (9560) notebook lineup. <u>MAC Installation</u> - Macbook PRO 15 - iMac OS: OS X (starting from Yosemite, to activate hardware rendering) <u>IOS Installation</u> - iPad PRO iPhone 7 Plus	Identical for a PC Installation with Windows OS. MAC and IOS Installation are not available for the subject device.
Features	- DICOM 2D/3D Reconstruction - Import and Matching STL Files - Implant Planning from Library - Surgical Guides Design - Connection with Lab Software - PC Version	- DICOM 2D/3D Reconstruction - Import and Matching STL Files - Implant Planning from Library - Surgical Guides Design - Connection with Lab Software - PC Version - <u>Segmentation of Anatomy and Dentures</u> - <u>MAC and Mobile Versions</u>	Similar

Principle of Operation	- Desktop application with intuitive step-by-step guidance	- Desktop application with intuitive step-by-step guidance	Similar Slightly differences in the GUI
Technical Data	- DICOM compliant Image Import Formats: DICOM, STL, OBJ,OFF - Image Export Formats: STL	- DICOM compliant - Image Import Formats: DICOM, STL, OBJ, OFF - Image Export Formats: STL	Same

Table 4: Device Comparison

CONCLUSION

Based on a comparison and discussion of indications for use, system requirements, features, principle of operation and technical/performance data the ZIRKONZAHN.Implant-Planner software is found to be substantially equivalent to the predicate device, as it is not raising any new questions of safety and effectiveness. Performance data are included in this premarket notification to demonstrate the effectiveness and safety of the subject device regarding its design, functional and safety requirements.