March 12, 2018

SICAT GmbH & Co. KG
% Frederik Kunze
Quality Management and Regulatory Affairs
Brunnenallee 6
Bonn, NRW 53177
GERMANY

Re: K180262
Trade/Device Name: SICAT Endo
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 29, 2018
Received: January 30, 2018

Dear Frederik Kunze:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K180262

Device Name
SICAT Endo

Indications for Use *(Describe)*

- Aiding diagnosis in the oral-maxillofacial region
- Aiding comparisons of different treatment options
- Aiding endodontic treatment planning
- Aiding treatment planning for endodontic 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.

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510(k) Summary
for
SICAT Endo

Content and format as required by section 21 CFR 807.92
(*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm*)

1. SUBMITTER/510(K) HOLDER

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Primary Contact: Mr. Dr. Manfred Breuer
Secondary Contact: Mr. Frederik Kunze

Date Prepared: January 29th, 2018

2. DEVICE NAME AND DEVICE CLASSIFICATION

Proprietary Name:	SICAT Endo
Common/Usual Name:	Radiological Visualization Software for Diagnosis and Dental Treatment Planning
Classification Name:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Classification Class:	Class II Product

3. PREDICATE DEVICES

- SICAT Implant (K103723) (Primary predicate device)
- 3D Endo™ Software (K171115)

4. DEVICE DESCRIPTION

SICAT Endo is a pure software device.

SICAT Endo is a software tool intended for viewing and analyzing medical information:

- medical 3D volume data such as volumetric X-ray data from Cone Beam CT (CBCT) and CT scanners, and
- intraoral images, and
- 3D optical surface data like optical impression data from optical scanners, and

SICAT Endo provides tools for analyzing the root canal and to mark it visually. It allows to define a drill canal and ordering of a corresponding surgical guide with a drill sleeve.

5. Indications for Use

Indications for use for SICAT Endo are:

- *Aiding diagnosis in the oral-maxillofacial region*
- *Aiding comparisons of different treatment options*
- *Aiding endodontic treatment planning*
- *Aiding treatment planning for endodontic surgical guides*

6. Device Comparison Table

The following table shows a summary of the intended use, technological characteristics, design and function of SICAT Endo and the predicate devices. The predicate device SICAT Implant is the primary predicate device.

	SICAT Endo	**3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)**	**SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
Common / Usual Name			
	Radiological Visualization Software for Diagnosis and Endodontic Treatment Planning	Radiological Visualization Software for Diagnosis and Endodontic Treatment and Re-treatment Planning	Radiological Visualization Software for Diagnosis and Dental Implant Planning
Device Description			
General Description	SICAT Endo is a pure software device. SICAT Endo is a software application for visualization of imaging information of the oral-maxillofacial region. The imaging data	3D Endo™ is a CBCT based software device designed to improve endodontic treatment planning for more predictability. It is designed to improve treatment quality: to isolate the tooth of interest, to	SICAT Implant V1.2 is a pure software device. SICAT Implant V1.2 is a software application for the visualization of imaging information of

	SICAT Endo	3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)	SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
	originates from medical scanners such as CT or CBCT scanners. It is also used as a software system to aid medical professionals with the planning, the evaluation and the comparison of treatment options and the planning of endodontic accesses for an endodontic treatment. The medical professionals' planning data may be exported from SICAT Endo and used for the realization of the planned therapy.	clearly visualize the tooth anatomy in 3D, to identify all canals and to anticipate areas. The use of 3D Endo provides: - Diagnosis and pathology - 3D tooth anatomy - Canal system - 3D canal anatomy - Treatment plan The Wizard allows to: • Diagnose the case; • Isolate the tooth of interest; • Investigate the canal system; • Understand the 3D Canal anatomy; • Create a Treatment plan. The use of 3D Endo allows to: • evaluate 3D working length and cavity access depth • locate canal orifices without opening the tooth • plan for an optimal cavity access and your final instrument • investigate canals' irregularities following their curvatures In addition, the simulated Intra-Root Camera View Visualize	the oral-maxillo-facial region. The imaging data originates from medical scanners such as CT or DVT scanners. SICAT Implant V1.2 is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. SICAT Implant V1.2 allows to name, position, move, rotate, resize and visualize dental implants and other planning objects (i.e. nerve canals) within the visualized 3D volume. Thus, dental professionals like implantologists are enabled to precisely plan the positions, orientations, types and sizes of implants to be placed in the patient's mandible/maxilla

	SICAT Endo	3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)	SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
		throughout the canal the theoretical cutting envelope of the Dentsply Sirona Endodontics instruments.	together with the related surgical procedures. The dental professionals' planning data may be exported from SICAT Implant V1.2 and used as input data for CAD or Rapid Prototyping Systems.
Indications for Use			
Indications for Use	Aiding diagnosis in the oral-maxillofacial region Aiding comparisons of different treatment options Aiding endodontic treatment planning Aiding treatment planning for endodontic surgical guides	3D Endo™ Software is intended to aid in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases utilizing DICOM images.	SICAT Implant is a software application for the visualization of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or DVT scanners. SICAT Implant is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. The dental professionals'

	SICAT Endo	3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)	SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
			planning data may be exported from SICAT Implant and used as input data for CAD or Rapid Prototyping Systems.
Contraindications	None	Do not use 3D Endo™ Software for implants or any other dental procedure outside endodontics. There are no known serious adverse reactions or potential safety hazards.	None
Medical Data Viewing			
Data types visualized	3D volume data, 3D surface data (optical impressions), 2D radiographs	2D and 3D visualized CBCT data	3D volume data, 3D surface data (optical impressions, implant objects)
Imaging data visualization region	Oral-maxillofacial region	Oral-maxillofacial region	Oral-maxillofacial region
Viewing Modes typically used for dental procedures			
***Orthogonal slices**	Axial, coronal, sagittal within the Endoline wizard	Axial	Axial, coronal, sagittal
***Panoramic view**	Panoramic view (ray sum) based on a panoramic curve. Panoramic curve can be manually adjusted.	No	Panoramic view (ray sum) based on a panoramic curve. Panoramic curve can be manually adjusted.
Curved Planar Reformation	Curved planar reformation based	Yes	None

	SICAT Endo	3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)	SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
(CPR) also called Multi Planar Reformation (MPR) that is less precise	on a spline positioned within the volume. By positioning the spline the view is adjusted. No equidistant scale.		
***Panoramic slice**	Movable "Panoramic Slicing Window" embedded in panoramic view	No	Movable "Panoramic Slicing Window" embedded in panoramic view
***TSA and LSA**	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve	Transversal slice	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve
***3D volume rendering**	Yes	Yes	Yes
***3D surface rendering of volume data**	Yes	No	Yes
2D radiographs on 3D volumetric data	Yes	No	No
Volume Data Navigation and Manipulation			
***View manipulating tools**	Zoom, Pan, Change of orientation	Zoom, Pan, Change of orientation	Zoom, Pan, Change of orientation
***Color manipulating tools**	Brightness, Contrast	Brightness, Contrast	Brightness, Contrast
***Scrolling through slices**	Yes	Yes	Yes
Measurements			
***Overall Length Measurement**	100 μm	± 0.5 mm	100 μm

	SICAT Endo	**3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)**	**SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
Accuracy			
***Overall Angular Measurement Accuracy**	1 degree	± 5°	1 degree
Optical Surface Data Visualization			
***Rendering of optical surface data**	Yes, 3D	No	Yes, 3D
Optical Surface Data Manipulation			
***Registration of surface data (from optical impressions) to volume data**	Semi-automatic, using user specified reference points.	n/a	Semi-automatic, using user specified reference points.
Input / Output (I/O)			
***Volume data import**	DICOM	DICOM	DICOM
***Optical surface data / optical impression import**	Standard STL format and proprietary SSI or SIXD container format. Features and Algorithms identical to SICAT Implant.	No	Standard STL format and proprietary SSI.
***Data Compression**	Lossless ZIP compression	n/a	Lossless ZIP compression
Export of data for realization of planned therapy	Yes	No	Yes
Main functions			
***Marking of root canal pathways**	Yes	Yes	No
Planning of drillpaths	Yes	No	Yes
Programming Language			
	C# and C++	no data available	C# and C++

	SICAT Endo	**3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)**	**SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
Minimum Technical Requirements			
PC Hardware requirements (minimum)	Operating System: Windows 7 64-bit SP1+ "Platform Update" KB2670838, Windows 8 64-bit (Desktop), Windows 8.1 64-bit (Desktop), Windows 10 64-bit CPU: Quad Core 2.3 GHz RAM: 8 GB HDD: 20 GB free space Video card: 1 GB RAM (dedicated), must support DirectX 11 or higher, feat driver WDDM 1.0 or higher, e.g. NVidia GTX 960 (2GB RAM) Screen: 1980x1080 (Full HD), Scaling 100 % - 125 %, Resolution max. 3840x2160, Scaling 100 % - 200 % must pass test with SMPTE Test pattern Additional requirements when running as SIDEXIS XG-DirectDental-Plug-In: Sidexis XG: Version 2.6.1 (64 Bit) or Sidexis 4, V 4.1.2 (64 Bit) Additional requirements when running as SIDEXIS 4 Module: SIDEXIS	Operation systems: Windows 7, 8.1 or 10; 64-bit Processor: 3rd Generation Intel® Core™ Processors or higher RAM: 4 GB or more Free disk space: 20 GB or more Graphical card requirements: On-board Intel® HD Graphics 2500 or higher Screen resolution: 1024 x 768 or better Open GL requirements: Version 3.2 or higher	Operating System: Windows XP Professional (32-bit) with SP3 and .NET 2.0 Runtime Libraries or Windows Vista Business (32-bit) with SP2 or Windows 7 Professional (32-bit or 64-bit) with SP1 CPU: Dual Core 1.6 GHz RAM: 2 GB Free space on HDD: 5 GB Video card: 128 MB external video card, 24-bit color, Shader Model 3 (for advanced 3D rendering) Screen resolution: 1280x1024 pixels

	SICAT Endo	3D Endo, Dentsply Sirona (marketed in EU / USA cleared under 510(k) K171115)	SICAT Implant, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
	4: Sirona Planning API V4 (starting with SIDEXIS V 4.2)		

* for functions and algorithms used in SICAT Implant and SICAT Endo having the same principle;

Missing features of SICAT Endo compared to the predicate device SICAT Implant are connected to implant planning. This does not impact the safety and effectiveness of SICAT Endo concerning the visualization of imaging information and treatment planning and evaluation.

Except for the CPR view the software algorithms used in SICAT Endo are similar to the predicate device SICAT Implant. Performance testing has been used to validate the safety and effectiveness of the SICAT Endo device in comparison to the predicate device 3D Endo regarding endodontic planning features, including the CPR view.

7. Non-Clinical Performance Testing and Verification and Validation Activities

For SICAT Endo, software verification and validation activities were performed, in accordance with the following guidance and standards:

- Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
- AAMI/ANSI/IEC 62304:2006, Medical device software - Software life cycle processes
- IEC 62366-1, Medical devices - Application of usability engineering to medical devices
- ISO 14971:2007, Medical devices - Application of risk management to medical devices.

Among others the following verification and validation activities were performed:

- Design Validation/Reviews
- Unit Tests
- Code Reviews
- Usability Tests
- Integration Tests
- System Verification Tests
- User Site Tests

Special bench testing has been performed with non-clinical data:

- to verify the endodontic planning visualization quality and effectiveness
- overall quantitative accuracy of the root canal treatment planning

Test reports for integration testing, system verification and validation testing and bench testing are included with this premarket notification.

A verification and validation activities summary report provided with this premarket notification concludes that SICAT Endo passed all verification and validation activities and that safety and effectiveness of the product has been demonstrated in the context of its intended use.

8. Conclusion

Based on the information and supporting documentation provided in the premarket notification, SICAT Endo is considered to be comparable in design, material and function to the predicate devices. It is believed to perform as well as the predicate devices for the visualization of imaging data together with optical impression data, the diagnostic purpose, and the technological approach of planning drill canals and the evaluation of dental treatment options. Any minor differences between SICAT Endo and the predicate devices do not effect safety and effectiveness.