SICAT GmbH & Co. KG
% Manfred Breuer
Head of Quality Management and Regulatory Affairs
Brunnenallee 6
53177 Bonn, NRW
GERMANY

December 4, 2019

Re: K192348
Trade/Device Name: SICAT Implant V2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 2, 2019
Received: October 7, 2019

Dear Manfred Breuer:

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)*
K192348

Device Name
SICAT Implant V2.0

Indications for Use *(Describe)*
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 CBCT scanners. SICAT Implant is intended for use as planning software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. The dental professionals' planning data can be exported from SICAT Implant. This planning data includes in particular the positions, orientations and types of implants and drill sleeves to be used in the surgical procedures. This data may be used as input to design and manufacture surgical guides for dental implants.

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 Implant V2.0
K192348

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. Markus Gratzfeld

Date Prepared: December 4th, 2019

2. DEVICE NAME AND DEVICE CLASSIFICATION

Proprietary Name:	SICAT Implant V2.0
Common/Usual Name:	Radiological Visualization Software for Diagnosis and Dental Implant Planning
Classification Name:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system
Product Code:	LLZ
Classification Panel:	Radiology
Regulation Number:	21 CFR 892.2050
Device Class:	Class II

3. PREDICATE DEVICE

Proprietary Name:	SICAT Implant V1.2
Manufacturer:	SICAT GmbH & Co. KG
510(k) number:	K103723

4. DEVICE DESCRIPTION

SICAT Implant V2.0 is a pure software device.

SICAT Implant V2.0 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 CBCT scanners.

SICAT Implant V2.0 is intended for use as planning software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments.

SICAT Implant V2.0 allows to name, position, move, rotate, resize and visualize dental implants and other planning objects (i.e. nerves) 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 together with the related surgical procedures.

The dental professionals' planning data can be exported from SICAT Implant. This planning data includes in particular the positions, orientations and types of implants and drill sleeves to be used in the surgical procedures. This data may be used as input to design and manufacture surgical guides for dental implants.

The modifications to SICAT Implant V1.2 (K103723) include the following:

- Complete reengineering including significant software re-write
- Added planning functionality
- Updated user interface

5. Indications for Use

Indications for use of SICAT Implant V2.0 are:

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 CBCT scanners. SICAT Implant is intended for use as planning software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. The dental professionals' planning data can be exported from SICAT Implant. This planning data includes in particular the positions, orientations and types of implants and drill sleeves to be used in the surgical procedures. This data may be used as input to design and manufacture surgical guides for dental implants.

6. Device Comparison Table

The modified device SICAT Implant V2.0 has the same intended use and fundamental scientific technology. A comparison of the proposed device SICAT Implant V2.0 to the currently marketed predicate device SICAT Implant V1.2 including intended use, technological characteristics, design and function is provided in the following table.

	SICAT Implant V2.0	**SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
Common/Usual Name		
	Radiological Visualization Software for Diagnosis and Dental Implant Planning	Radiological Visualization Software for Diagnosis and Dental Implant Planning

	SICAT Implant V2.0	**SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
Device Description		
General Description	SICAT Implant V2.0 is a pure software device. SICAT Implant V2.0 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 CBCT scanners. SICAT Implant V2.0 is intended for use as planning software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. SICAT Implant V2.0 allows to name, position, move, rotate, resize and visualize dental implants and other planning objects (i.e. nerves) 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 together with the related surgical procedures. The dental professionals' planning data can be exported from SICAT Implant. This planning data includes in particular the positions, orientations and types of implants and drill sleeves to be used in the surgical procedures. This data may be used as input to design and manufacture	SICAT Implant V1.2 is a pure software device. SICAT Implant V1.2 is a software application for the visualization of imaging information of 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 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.

	SICAT Implant V2.0	**SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
	surgical guides for dental implants.	
Indication for use/Intended use		
Indications for Use/ Intended use	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 CBCT scanners. SICAT Implant is intended for use as planning software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. The dental professionals' planning data can be exported from SICAT Implant. This planning data includes in particular the positions, orientations and types of implants and drill sleeves to be used in the surgical procedures. This data may be used as input to design and manufacture surgical guides for dental implants.	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' planning data may be exported from SICAT Implant and used as input data for CAD or Rapid Prototyping Systems.
Contraindications	None	None
Medical data viewing		
Data types visualized	3D volume data, 3D surface data (optical impressions, restorations, implant objects)	3D volume data, 3D surface data (optical impressions, implant objects)
Imaging data visualization region	Oral-maxillofacial region	Oral-maxillofacial region
Viewing modes		
***Orthogonal slices**	Axial, coronal, sagittal	Axial, coronal, sagittal

	SICAT Implant V2.0	**SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
***Panoramic view**	Panoramic view (ray sum) based on a panoramic curve. Panoramic curve can be manually adjusted.	Panoramic view (ray sum) based on a panoramic curve. Panoramic curve can be manually adjusted.
***Panoramic slice**	Movable small or not movable maximized "Panoramic Slicing Window" embedded in panoramic view	Movable "Panoramic Slicing Window" embedded in panoramic view
***TSA and LSA**	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve panoramic view	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve
***** **3D volume rendering**	Yes	Yes
***** **3D surface rendering of volume data**	Yes	Yes
Volume Data Navigation and Manipulation		
***View manipulating tools**	Zoom, Pan, Change of orientation	Zoom, Pan, Change of orientation
***Color manipulating tools**	Brightness, Contrast	Brightness, Contrast
***Scrolling through slices**	Yes	Yes
Volume orientation	Yes	Yes
Measurements		
***Length measurement**	Yes	Yes
***Angle measurement**	Yes	Yes
***Overall Length Measurement Accuracy**	100 μm	100 μm
***Overall Angular Measurement Accuracy**	1 degree	1 degree
Density	No	Yes, relative grey values

	SICAT Implant V2.0	**SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
Optical surface data visualization		
***Optical impression (maxilla, mandible, or a part thereof)**	Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in some slice views	Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in some slice views
Optical impression identification	Names of loaded optical impression in object browser.	A list view in a dedicated toolbar contains the names of all loaded optical impressions.
***Restoration model**	Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in slice views.	Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in slice views.
Restoration model identification	Names of loaded restoration model in object browser, hierarchically sorted according to the corresponding optical impressions.	A list view in a dedicated toolbar contains the names of all loaded restorations, hierarchically sorted according to the corresponding optical impressions.
***Show/Hide a surface object**	Yes Visibility applies to all views simultaneously.	Yes Visibility applies to all views simultaneously.
***Rendering of optical surface data**	Yes, 3D	Yes, 3D
Optical surface data manipulation		
***Registration of surface data (optical impressions) to volume data**	Semi-automatic, using user specified reference points.	Semi-automatic, using user specified reference points.
***Fine tuning the accuracy of the registration**	Restart of the registration with a different set of reference points.	Restart of the registration with a different set of reference points.
Delete	Yes, each loaded optical surface dataset separately. Restorations are deleted together with their associated optical impression.	Yes, each loaded optical impression separately. Restorations are deleted together with their associated optical impression.
Input/Output (I/O)		
***Volume data import**	DICOM	DICOM

	SICAT Implant V2.0	**SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)**
***Optical surface data / optical impression import**	Standard STL format and proprietary SSI or SIXD container format.	Standard STL format and proprietary SSI.
Data Import/Export	A "study" consisting of planning data, volume data and optical surface data may be exported and imported in a SICAT proprietary format.	Proprietary: Planning, volume and surface data.
***Data Compression**	Lossless ZIP compression	Lossless ZIP compression
***** **Export of data for realization of planned therapy**	For Surgical guide design and production by the SICAT dental laboratory or a third party manufacturer.	For Surgical guide design and production by the SICAT dental laboratory
Export of planning report	PDF	PNG
Implant visualization		
***** **Body**	Polygonal mesh (conical frustum) in 3D view and cut through polygonal mesh in planar slice views.	Polygonal mesh (conical frustum) in 3D view and cut through polygonal mesh in planar slice views
***** **Axis**	Line in 3D view and projected line in planar slice views	Line in 3D view and projected line in planar slice views
Identification	Name (tooth number) of implants in object browser	Name (tooth number) of active implant in toolbar
Dimensions (occlusal diameter, apical diameter, length)/Models	Dimensions/Models of implants in object browser and of active implant in properties area.	Dimensions of (active) implant in toolbar.
Implant database		
Implant database	Realistic geometric data of manufacturer implants, abutments and sleeves	Realistic geometric data of manufacturer implants
Implant manipulation and planning		
***** **Plan/insert realistic manufacturer and generic implants**	Via workflow toolbar 1-click in all planar slice views and in the panoramic view.	1-click in all planar slice views and in the panoramic view.
***** **Plan/insert realistic**	Via workflow toolbar 1-click with a rough implant pre-positioning based on	1-click with a rough implant pre-positioning at the site of the restoration

	SICAT Implant V2.0	SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
manufacturer and generic implants based on a restoration included in the optical surface data	the position and orientation of the restoration.	
Delete implants	All implants or active implant via object browser	Active implant via toolbar or context menu
*** Move implants**	Active implant in all planar slice views and in the panoramic view	Active implant in all planar slice views
*** Rotate implants**	Active implant about both end points in all planar slice views	Active implant about both end points in all planar slice views
Change implant dimensions/models	Via object browser and properties area.	Via toolbar or context menu
Change identification	Tooth number of (active) implant via tooth chart	Tooth number via tooth chart
Safety margin visualization	For all implants in all views	For active implant in all views
Mandibular nerve visualization		
*** Nerve**	Polygonal mesh (tube) in 3D view and panoramic view and cut through polygonal mesh in planar slice views	Polygonal mesh (tube) in 3D view and panoramic view and cut through polygonal mesh in planar slice views
Mandibular nerve manipulation		
Insert	Manual definition of a sequence of spline control points in all planar slice views	Manual definition of a sequence of spline control points in all planar slice views
Delete	Via object browser.	Via toolbar
Insert control point	In all planar slice views.	In all planar slice views
Delete control point	Via properties area.	Via toolbar
Move control point	In all planar slice views.	In all planar slice views
Change diameter	Via properties area.	Via toolbar
Abutment visualization		
Body	Polygonal mesh in 3D view and cut through polygonal mesh in planar slice views.	No

	SICAT Implant V2.0	SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
Identification	Tooth number of corresponding implant in object browser	No
Dimensions/Models	Dimensions/Models of abutments in object browser and of active abutment in properties area.	No
Abutment manipulation and planning		
Add compatible realistic manufacturer abutments	Via workflow toolbar for compatible planned implants.	No
Add generic abutments for planned implants	Via workflow toolbar for planned implants.	No
Delete abutments	Active abutment via object browser	No
Change abutment dimensions/models	Via object browser and properties area.	No
Change identification	N/A, Identification via corresponding implant	No
Sleeve visualization		
Body	Polygonal mesh in 3D view and cut through polygonal mesh in planar slice views.	No
Identification	Tooth number of corresponding implant in object browser	No
Dimensions/Models	Dimensions/models of sleeve in object browser and for active sleeve in properties area.	No
Sleeve manipulation		
Add realistic manufacturer sleeves	Via workflow toolbar or plan area for compatible planned implants	No
Delete sleeves	All sleeves via object browser and plan area	No
Change sleeve dimensions/models	Via object browser, properties area and plan area.	No

	SICAT Implant V2.0	SICAT Implant V1.2, SICAT (marketed in EU / USA cleared under 510(k) number K103723)
Change sleeve position	Via planar slice views, object browser and properties area	No
Change identification	N/A, Identification via corresponding implant	No
Documentation		
Generation of planning report for documentation	Yes	Yes
Technical Information		
Programming Language	C# and C++	C# and C++
PC Hardware & Software requirements (minimum)	Operating System: Windows 7 64-bit SP1+ "Platform Update" KB2670838, Windows 8.1 64-bit (Desktop), Windows 10 64-bit (Desktop) CPU: Quad Core 2.3 GHz RAM: 8 GB HDD: 20 GB free space Video card: 2 GB RAM (dedicated), must support DirectX 11 or higher, feat driver WDDM 1.0 or higher, e.g. NVidia GTX 960 (2GB RAM) Screen: Resolution min. 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 4 Module: SIDEXIS 4.3.1 or higher, Sirona Planning API (SiPlanAPI) V5	Operating System: Windows XP with SP2 and .NET 2.0 Runtime Libraries or Windows Vista 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 CD-Writer, network interface card (100 MBit/s, 1 GBit/s recommended), keyboard, mouse

* for functions and algorithms used in SICAT Implant V2.0 and SICAT Implant V2.0 having the same principle;

The software algorithms used in SICAT Implant V2.0 are equal or similar to algorithms used in the predicate device SICAT Implant V2.0.

The added abutment planning functionality is for visualization purposes and the dentist determines if the abutment offers a reasonable starting point for possible future prosthetics. Within SICAT Implant, the user is not able to design any abutments or parts thereof. Furthermore, within SICAT Implant the user is not able to design a dental restauration such as a crown. There is no kind of output at all for the design of the abutment or a dental restauration such as a crown.

The modifications to the predicate device SICAT Implant V1.2 do not affect safety and effectiveness of the proposed device SICAT Implant V2.0.

Based on this information, SICAT GmbH & Co. KG believes that SICAT Implant V2.0 described in this submission is substantially equivalent to the predicate device SICAT Implant V1.2.

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

No performance standards applicable to this device have been adopted under Section 514 of the Act.

Risk management has been ensured via risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. SICAT GmbH & Co. KG adheres to recognized and established medical industry standards for development including ISO 13485, IEC 62304 and IEC 62366. The device is designed and manufactured in accordance with Quality Systems Regulations as outlined in 21 CFR 820.

Verification and validation activities have been successfully performed on the software, including assurance that functions work as designed, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented.

Among others the following verification and validation activities were performed:

- Requirements Reviews
- Design Validation/Reviews
- Risk Management
- Software verification and validation including
    - Unit Tests
    - Code Reviews
    - Usability Tests
    - Integration Tests
    - System Verification and Validation Tests

For SICAT Implant V2.0, 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
- ISO 14971:2007-Ed.2 Medical devices - Application of risk management to medical devices
- AAMI/ANSI/IEC 62304:2006, Medical device software - Software life cycle processes
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes

- IEC 62366-1 Edition 1.0 2015-02 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)]

The above-mentioned verification and validation activities concluded that SICAT Implant V2.0 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 Implant V2.0 is considered to be comparable in design, material and function to the predicate device SICAT Implant V1.2. It is believed to perform as well as the predicate device for the visualization of imaging information of the oral-maxillofacial region together with optical impression data, the diagnostic purpose and the planning functionality to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. Any minor differences between SICAT Implant V2.0 and the predicate device do not affect safety and effectiveness.