K103723
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MAY 20 2011

510(k) Summary
for the
SICAT GmbH & Co. KG
SICAT Implant V 1.2

(per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

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Germany

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Primary Contact: Mr. Dr. Manfred Breuer
Secondary Contact: Mr. Markus Pfister

Date Prepared: December 16, 2010

2. DEVICE NAME AND DEVICE CLASSIFICATION

Proprietary Name:	SICAT Implant V 1.2
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
Regulation Number:	892.2050
Classification Class:	Class II Product

3. PREDICATE DEVICES

- SICAT Implant (V 1.0 incl. SP1), K090119
- Materialise SimPlant V 12.0 with OMS Module, K033849, K053592, K081402

4. DEVICE DESCRIPTION

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-maxillofacial 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.

5 INTENDED USE

SICAT Implant V1.2 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 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. The dental professionals' planning data may be exported from SICAT Implant V1.2 and used as input data for CAD or Rapid Prototyping Systems.

6 SUBSTANTIAL EQUIVALENCE

The SICAT Implant V1.2 system is substantially equivalent to the SimPlant System (K033849, K053592, K081402) and the SICAT Implant (V1.0 incl. SP1) System (K090119) based on the equivalence of the intended use, similar features and technical characteristics.

Performance testing to validate the safety and effectiveness of the SICAT Implant V1.2 system included validation testing and bench tests of the software functions.

7 CONCLUSION

SICAT Implant V1.2 is considered to be substantially equivalent to the SimPlant System and the SICAT Implant (V1.0 incl. SP1) System.

Based on the information and supporting documentation provided in the premarket notification, the SICAT Implant V1.2 is substantially equivalent to the predicate devices in design, material and function. Testing demonstrates that the SICAT Implant V 1.2 fulfills prospectively defined design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SICAT GMBH & Co. KG
% Mr. Mark Sheehan
Regulatory Associate
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

MAY 20 2011

Re: K103723
Trade/Device Name: SICAT Implant V 1.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 16, 2010
Received: December 21, 2010

Dear Mr. Sheehan:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103723

Device Name: SICAT Implant V 1.2

Indications for Use:

The SICAT Implant V 1.2 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. The SICAT Implant V 1.2 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. The dental professionals' planning data may be exported from SICAT Implant V 1.2 and used as input data for CAD or Rapid Prototyping Systems.

Prescription Use X AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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