K090119

510(k) Summary

for

FEB - 5 2009

SICAT Implant

1 Company Name and Address

1.1 Sponsor

siCAT GmbH & Co. KG
Brunnenallee 6
D-53177 Bonn
Germany

Manufacturer

siCAT GmbH & Co. KG
Brunnenallee 6
D-53177 Bonn
Germany
Registration Number: 3006098230
Operations: Manufacturer
Status: Active

1.2 Contact

siCAT GmbH & Co. KG
Brunnenallee 6
D-53177 Bonn
Germany

Telephone: +49-228/854 697 84
Facsimile: +49-228/854 697 99

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

2 Device Name and Classification

Proprietary Name:	SICAT Implant
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 Device

The SICAT Implant is claimed to be substantially equivalent in material, design and function to the SimPlant System product which was cleared by FDA under 510(k) K033849 on May 25, 2004 and the GALILEOS Implant product which was cleared by FDA under 510(k) K061472 on June 9, 2006.

4 Device Description

SICAT Implant is a pure software device.

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.

SICAT Implant 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 and used as input data for CAD or Rapid Prototyping Systems.

5 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 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.

6 Substantial Equivalence

The SICAT Implant system is substantially equivalent to the SimPlant System (K033849) and the GALILEOS Implant System (K061472) 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 system included validation testing and bench tests of the software functions.

7 Conclusion

SICAT Implant is considered to be substantially equivalent in design, material and function to the SimPlant System and the GALILEOS Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

siCAT GmbH & Co., KG
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K090119
Trade/Device Name: SICAT Implant
Regulation Number: 21 CFR 878.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 16, 2009
Received: January 21, 2009

Dear Mr. Preiss:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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; 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 INDICATIONS FOR USE STATEMENT

for
SICAT Implant

510(k) Number (if known): K090119

Device Name: SICAT Implant

Indications for 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 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090119