K061472

510(k) Summary

for

GALILEOS Implant

1 Company Name and Address

JUN - 9 2006

1.1 Sponsor

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

Manufacturer

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

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

Proprietary Name:	GALILEOS Implant
Common/Usual Name:	Preoperative Dental Implant Planning Software
Classification Name:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system

3 Predicate Device

The GALILEOS 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.

4 Device Classification

Picture archiving and communications systems (21 CFR 892.2050, Product Code LLZ) have been classified as Class II devices and are reviewed by the Radiology Panel.

5 Device Description

GALILEOS Implant is a pure software device.

GALILEOS Implant is an Add-On to the 3D-viewing software Sirona GALAXIS. GALILEOS Implant adds features for pre-operative simulation / evaluation of dental implant placement and surgical treatment options. GALILEOS Implant allows to name, position, move, rotate, resize and visualize generic dental implants and other planning objects (i.e. nerve canals) within the 3D volume data visualized by Sirona GALAXIS. 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.

6 Intended Use

GALILEOS 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 implant treatments. GALILEOS Implant is based on medical imaging information presented by the Sirona GALAXIS 3D viewer and produced by Sirona GALILEOS medical cone beam scanner. The dental professionals' input information may be exported from GALILEOS Implant and used as input data for CAD or Rapid Prototyping Systems.

7 Substantial Equivalence

The GALILEOS Implant system is substantially equivalent to the SimPlant System (K033849) based on the equivalence of the intended use, similar features and technical characteristics. Performance testing to validate the safety and effectiveness of the GALILEOS Implant system included validation testing and bench tests of the software functions.

8 Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 9 2006

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

Re: K061472
Trade/Device Name: GALILEOS Implant
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 26, 2006
Received: May 30, 2006

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 (Premarket Approval), 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 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 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 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
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
GALILEOS Implant

510(k) Number (if known): K061472

Device Name: GALILEOS Implant

Indications for Use:

GALILEOS 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 implant treatments. GALILEOS Implant is based on medical imaging information presented by the Sirona GALAXIS 3D viewer and produced by Sirona GALILEOS medical cone beam scanner. The dental professionals' input information may be exported from GALILEOS 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)

David G. Seegran

(Division Sign-Off)
Division of Reproductive Abdominal
and Radiological Devices
510(k) Number K061472