FEB 8 2006 K053592

SECTION 7
SPECIAL 510(K) PREMARKET NOTIFICATION SUMMARY

SUBMITTER'S NAME AND ADDRESS: MATERIALISE N.V.
Technologielaan 15
B-3001 LEUVEN, BELGIUM

ESTABLISHMENT REGISTRATION NO: 3003998208

CONTACT PERSON: Carl Van Lierde, Materialise N.V.
Quality Manager
+32 163 967 14 (tel)
+32 163 966 00 (fax)
carl.vanlierde@materialise.be

SUMMARY PREPARATION DATE: November 22, 2005

TRADE NAME: SimPlant System; SimPlant - Dr James

COMMON NAME:

Image processing system and preoperative software for simulating /evaluating dental implant placement and surgical treatment options

CLASSIFICATION NAME:

System, Image Processing. This product uses images acquired from Computerized Tomography (CT) scanners.

PREDICATE DEVICE: SimPlant System (K033849)

FUNCTION

The modified SimPlant System is used to transfer images from a medical scanner and to perform a segmentation of the images. It is also used to provide a means for pre-operative planning. Surgical templates may be fabricated based on the output of the pre-operative planning.

INTENDED USE

The SimPlant System is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.

TECHNOLOGICAL COMPARISON OF DEVICES

Feature	Modified SimPlant System (Dr. James)	SimPlant System
Material	Software – magnetic media	Software – magnetic media
Design	Software for use in pre-operative planning.	Software for use in pre-operative planning
Function	SimPlant System is used to provide a means for image segmentation and pre-operative planning. Offers extended assistance for dental implant planning Surgical templates may be fabricated based on the output of the pre-operative planning	SimPlant System is used to provide a means for image segmentation and pre-operative planning. Surgical templates may be fabricated based on the output of the pre-operative planning

CONCLUSION

The modified SimPlant System is considered to be substantially equivalent in design, material and function to the unmodified SimPlant System. It is believed to perform as well as the predicate device for pre-operative planning and for image segmentation. Accordingly, we respectfully request the Agency to expeditiously find this special 510(k) premarket notification to be Substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2006

Mr. Carl Van Lierde
Quality Manager
Materialise N.V.
Technologielaan 15
Leuven 3001
BELGIUM

Re: K053592
Trade/Device Name: SimPlant System (Dr. James)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 26, 2006
Received: January 26, 2006

Dear Mr. Van Lierde:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 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

Indications for Use

510(k) Number (if known): K053592

Device Name: SimPlant System (Dr. James)

Indications For Use:

The Materialise **SimPlant System** is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also used as a pre-operative software for simulating /evaluating dental implant placement and surgical treatment options.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053592