MAY 2 5 2004

## SUMMARY OF SAFETY AND EFFECTIVENESS
## MATERIALISE SIMPLANT SYSTEM

K033849

PROPRIETARY NAME:

**SimPlant System**

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.

DEVICE CLASSIFICATION:

This device has been classified as Class II.

REGULATORY CLASS:

Class II

PRODUCT CODE:

LLZ

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

ESTABLISHMENT REGISTRATION NO: Applied for

CONTACT PERSON: Carl Van Lierde, Materialise N.V.
Quality Manager

SUMMARY PREPARATION DATE: November 28, 2003

PREDICATE DEVICE

The **SimPlant System** is claimed to be substantially equivalent in material, design, and function to the SIM/Plant product which was acquired by Materialise from Columbia Scientific, Inc. and cleared by FDA under 510(k) K924810 on January 15, 1993.
The **SimPlant System** is claimed to be substantially equivalent in material, design, and function to the CT-Modeller product from Materialise which was cleared by FDA under 510(k) K970617 on April 21, 1997

DEVICE DESCRIPTION

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 intended as a pre-operative software for simulating / evaluating dental implant placement and surgical treatment options.

STERILIZATION

The **SimPlant System** is provided non-sterile.

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 intended as a pre-operative software for simulating / evaluating dental implant placement and surgical treatment options.

SUBSTANTIAL EQUIVALENCE

The **SimPlant System** is considered to be substantially equivalent to the SIM/Plant product and to the CT-Modeller System.

CONCLUSION

The **SimPlant System** is considered to be substantially equivalent in design, material and function to the SIM/Plant product and the Ct-Modeller System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2004

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

Re: K033849
Trade/Device Name: SimPlant System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 6, 2004
Received: April 8, 2004

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 (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 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 the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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): K033849

Device Name: SimPlant System

Indications for Use:

The SimPlant system is indicated for use as a is a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is indicated 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 indicated for use as a planning and simulation software for dental implant placement and surgical treatment.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033849