K060950

MAY 18 2006

SUMMARY OF SAFETY AND EFFECTIVENESS
MATERIALISE SIMPLANT SYSTEM

PROPRIETARY NAME:

3Matic

COMMON NAME:

Software for computer assisted design and manufacturing of medical and dental prostheses

CLASSIFICATION NAME:

Picture Archiving and Communications System

DEVICE CLASSIFICATION:

21 CFR 892.2050.

REGULATORY CLASS:

Class II

CLASSIFICATION PRODUCT CODE:

LLZ

SUBSEQUENT PRODUCT CODES:

NOF

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

SUMMARY PREPARATION DATE: March 21, 2006

PREDICATE DEVICE

3Matic is claimed to be substantially equivalent in material, design, and function to the SimPlant System, which was cleared by FDA under 510(k) K033849 on May 25, 2004.
3Matic is claimed to be substantially equivalent in material, design, and function to the Etkon ES-1 product from Etkon, which was listed with FDA on January 4, 2005.

INDICATIONS FOR USE

Materialise's **3Matic** is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-prostheses, patient specific medical and dental/orthodontic accessories and dental restorations.

STERILIZATION

The **3Matic** is provided non-sterile.

SUBSTANTIAL EQUIVALENCE

The **3Matic** is considered to be substantially equivalent to the SimPlant System and Etkon ES-1.

CONCLUSION

The **3Matic** is considered to be substantially equivalent in design, material and function to the SimPlant System and Etkon ES-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Carl Van Lierde
Quality Manager
Materialise NV
Medical Division
Technologielaan 12, Leuven 3001
BELGIUM

MAY 18 2006

Re: K060950
Trade/Device Name: 3Matic
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 27, 2006
Received: April 6, 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

K060950

Indications for Use

510(k) Number (if known):

Device Name: 3Matic

Indications For Use:

Materialise's **3Matic** is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-prostheses, patient specific medical and dental/orthodontic accessories and dental restorations.

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. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060950