MAR 3 1 2006

K052424

510(k) Summary

(1) Contact Information

This 510(k) is being submitted by Joseph Azary on behalf of Medicim NV.

Submitter / Regulatory Consultant: Joseph Azary, 543 Long Hill Avenue, Shelton, CT 06484, Tel: 203-944-9320, Fax: 203-944-9317

Applicant / Sponsor: Medicim NV, Callaertstraat 49, B-9100 Sint-Niklaas, Belgium. FDA Establishment Registration pending.

(2) Device Information

Trade or Proprietary Name: Maxilim

Common, Usual, and Classification Name: Image Processing System, Preoperative Software, System, Image Processing

(3) Predicate Devices:

The predicate devices are identified as the following: Simplant System by Materialise NV, 510(k) K033849. The subject device and predicate device have the same indications for use (planning for surgical treatment), similar technology, and both are 3-D and utilize CT images.

(4) **Intended Use:**

Maxilim is indicated 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. It is also indicated for use as a planning and simulation software for surgical treatment, specifically maxillofacial procedures.

(5) Technological Characteristics: The device is a software device (minor level of concern) with minimal risk to the patient. The device does not make contact with the patient. The device is used to assist physicians in the planning of surgical treatments, but is not meant to replace the professional judgment of the physician. The device is substantially equivalent to the predicate device.

(6) Conclusion: We believe the differences are minor and conclude that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2006

Medicim NV
% Mr. Joseph Azary
Azary Technologies, LLC
543 Long Hill Avenue
SHELTON CT 06484

Re: K052424
Trade/Device Name: Maxilim
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 8, 2006
Received: March 10, 2006

Dear Mr. Azary:

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): K052424

Device Name: Maxilim

Indications For Use:

Maxilim is indicated 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. It is also indicated for use as a planning and simulation software for surgical treatment, specifically maxillofacial treatment.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon Page 1 of ____
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052424