OCT 2 0 2004 K042383

12. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submission in accordance with the requirements of 21 CFR Part 807.87(h)

1. Submitter	: Medis medical imaging systems b.v.
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Contact Person	: J.I. Hollander, Quality Coordinator
Prepared	: August 25, 2004
2. Device Name	: Roentgen Stereophotogrammetric Analysis - CMS
Common Name	: **RSA-CMS**
Device Class. Name	: System Image Processing, Radiological.
Regulation Number	: 21 CFR 892.2050 (90 LLZ; Class II)
3. Predicate Device(s)	: Ortho-CMS of Medis **K041162**

4. Description of the device:

In orthopaedics clinical practice, loosening of prostheses is assessed indirectly by measuring radiolucent lines around the prosthesis and position differences of the prosthesis relative to the bone measured in successive radiographs. Radiolucent lines indicate the existence of a fibrous layer. However, these measurements are not very accurate: radiolucency may occur in areas that are occluded by the metal of the implant and the amount of radiolucency can be underestimated. Migration of the prosthesis is assessed by measuring changes in the relative positions of prosthetic landmarks and bony landmarks over time.

In 1974, Selvik developed a very accurate technique for the assessment of three-dimensional migration of prostheses. The technique was denoted Roentgen Stereophotogrammetric Analysis (RSA). The reported accuracy of RSA ranges between 0.05 and 0.5 mm for translations and 0.15° and 1.15 ° for rotations (95%-confidence interval). Because of the high accuracy of RSA, small patient cohorts can be sufficient to study the effect on prosthetic fixation due to changes in implant design, addition of coatings, new surgical techniques, and new bone cements.

RSA is the most accurate radiographic technique for the assessment of three-dimensional micromotion of orthopaedic implants. RSA-CMS is a software package that automatically performs RSA measurements in digital images. This software package runs on a PC with the Windows 2000 or XP operating system.

5. Intended use:

RSA-CMS has been developed for the objective and reproducible analysis on digital roentgen images (DICOM CR or DX) or digitised images in a PACS environment.

Orthopaedic specialist and core labs use the RSA-CMS standalone analytical software package in image post-processing for the evaluation of new implant designs, coatings and new cementation techniques in clinical trials.

When interpreted by trained physicians these parameters may be useful to derive conclusions from these clinical trials.

RSA-CMS is developed in close cooperation with the Division of Image Processing (LKEB) and the Department of Orthopaedics of the Leiden University Medical Center. It has been validated and complies with international safety and quality standards.

6. Substantial equivalence Information:
RSA-CMS is substantially equivalent to the Predicate Device of Medis medical imaging systems b.v, using the same technological technique for the same intended use.

Conclusion respecting safety and effectiveness:
It is the opinion of Medis medical imaging systems bv that RSA-CMS is safe and potential hazards are controlled by a risk management plan for the software development process, including hazard analysis, verification and validation tests. Evaluations by hospitals and literature support this statement. The software package RSA-CMS itself will not have any adverse effects on health. This tool calculates the relative motion of prosthesis with respect to the bone. The operator interprets the results of the analysis and chooses to accept or reject the results.
It is the opinion of Medis medical imaging systems b.v. that the level of concern for the stand alone software to view images is 'minor' and that the use of RSA-CMS software does not change the intended use of X-ray equipment in practice, nor does the use of software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

Mr. J. I. Hollander
Quality Coordinator
Medis Medical Imaging Systems bv
Schutterveld 9 2316 XG Leiden
P.O. Box 384 2300 AJ Leiden
THE NETHERLANDS

Re: K042383
Trade/Device Name: RSA-CMS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 25, 2004
Received: September 1, 2004

Dear Mr. Hollander:

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/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

510(k) Number (if known): K042383

Device Name: RSA - CMS

Indications For Use:

RSA-CMS has been developed for the objective and reproducible analysis on digital roentgen images (DICOM CR or DX) or digitised images in a PACS environment.
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042383

Prescription Use ✓