JUL 27 2004

K041162

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 bv
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Contact Person	: J.I. Hollander, Quality Coordinator
Prepared	: April 26, 2004
2. Device Name	: Medis Ortho-CMS
Common Name	: **Ortho-CMS**
Device Class. Name	: System Image Processing, Radiological
Regulation Number	: 21 CFR 892.2050 (90 LLZ; Class II)
3. Predicate Device(s)	: Meridian Technique Ltd: 510(k) **K032401** eFilm Medical Inc.: 510(k) **K020995**

4. Description of the device:

In orthopaedics, radiographs are used to diagnose and analyse various kinds of orthopaedic disorders, generative joint conditions, and bone fractures, and to evaluate orthopaedic treatments such as osteotomies and total joint arthroplasty. These arthroplasties need to be evaluated in order to assess the quality of the procedure. Measurements on radiographs of endoprostheses include the assessment of radiolucent lines around the prosthesis, bone growth or bone resorption, position of the prosthesis, motion of the prosthesis relative to the surrounding bone, and the determination of wear of the polyethylene components.

Since the measurements on radiographs are commonly performed manually, considerable intra-observer and inter-observer variation exists. Automation of the measurements might increase the objectivity and speed of the analysis, and decrease the variation of the results. In radiology, digital roentgen imaging techniques are increasingly being used over plain film radiographs. The digital roentgen images (DICOM CR or DX) are easily accessible from a medical picture archive (PACS) through a network connection.

Ortho-CMS supports the radiologist by facilitating the diagnosis of orthopaedic digital images and allows the orthopaedic specialist to perform a pre-surgical planning and a post-surgical evaluation on these images. Further, Ortho-CMS can be deployed as a measurement tool for core-labs that focus on quality assessment of orthopaedic implants or it can be used by bone centres that need to make measurements in donor bone images for joints replacement purposes.

5. Intended use:

Ortho-CMS is an orthopaedic analysis software tool. It has been developed to optimize preoperative planning through digital prosthesis templating and to enable preoperative and postoperative measurements in digital or digitized X-Ray images. Ortho-CMS software is meant solely for use by trained medical personnel.

- The intended purposes of Ortho-CMS are:
- Displaying of X-Ray images
- Supporting planning of joint replacement operations
- Supporting clinical diagnoses on implant loosening
- Enabling preoperative and postoperative measurements for clinical and research purposes

6. Substantial equivalence Information:

Ortho-CMS is substantially equivalent to the Predicate Devices of Meridian Technique Ltd, K032401 "Orthoview™" and of eFilm Medical Inc., K020995 "eFilm™ Workstation™", 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 Ortho-CMS is safe and potential hazards are controlled by a risk management plan for the software development process (**See Appendix C**), including hazard analysis (**See Appendix D**), verification and validation tests (**See Appendix E**). Evaluations by hospitals and literature (**See Appendix F**) support this statement. The software package Ortho-CMS itself will not have any adverse effects on health. This tool supports the radiologist by facilitating the diagnosis of orthopaedic digital images and allows the orthopaedic specialist to perform a pre-surgical planning and a post-surgical evaluation on orthopaedic images. The analyses results will be interpreted by the operator, who can choose to accept or reject the tools results.

It is the opinion of Medis medical imaging systems bv that the level of concern for the stand alone software to view images is 'minor' and that the use of Ortho-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

JUL 27 2004

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

Re: K041162
Trade/Device Name: Ortho-CMS
Regulatory Number: 21 CFR 892.2050
Regulatory Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 26, 2004
Received: May 3, 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 (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

510(k) Number (if known): K041162

Device Name:

Indications For Use:

Ortho-CMS is an orthopaedic analysis software tool. It has been developed to optimize preoperative planning through digital prosthesis templating and to enable preoperative and postoperative measurements in digital or digitized X-Ray images. Ortho-CMS software is meant solely for use by trained medical personnel.

- The intended purposes of Ortho-CMS are:
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041162