K032401

AUG 14 2003

510k Summary of Safety and Effectiveness

Date of Submission	9th June 2003
Submitter Name and Address	Meridian Technique Ltd Pinewood Chineham Business Park Basingstoke Hampshire RG24 8AL Great Britain
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Telephone	011 44 1235 817758
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Classification Name	Image Processing System
Common Name	Picture Archiving and Communication (PACS) System
Proprietary Name	Orthoview™
Predicate Device	510k reference K020995

Substantial equivalence is claimed between Orthoview™ and the templating, overlaying and image viewing elements only of:

eFilm Workstation with Modules
eFilm Medical inc
500 University Avenue Suite 300
Toronto
Ontario - Canada M5G 1V7

Device Description - Orthoview™ is a software device that permits the orthopedic surgeon to pre-plan surgical procedures by permitting image viewing and manipulation and prosthetic template overlay within a PACS workstation or standalone environment.

Intended Use - The Orthoview™ system is designed with the intention that licensed medical professionals can access digitised medical X-Ray images in DICOM or other formats obtained from a variety of modalities such as PACS systems, X-Ray digitisers etc.

This permits the review of such images and allows the overlay of digitised images of templates for prosthetic devices thereby providing an alternative to traditional means of optically viewing processed X-Ray films overlaid with the acetate templates of such prostheses supplied by the prosthetic manufacturer.

Orthoview™ provides the means of recording, storing and retrieving the templating process steps performed by the licensed medical professional when assessing the optimum prosthetic device for a particular patient.

The Orthoview™ system does not have any function such as image acquisition, image storage etc, this is the responsibility of the systems alongside which Orthoview™ operates. The Orthoview™ system does not specify the requirements for the prosthetic template – this is the responsibility of the prosthetic manufacturer.

Assessment of Non-clinical Performance Data

The comparison of intended performance versus actual performance was carried out by experienced healthcare professionals using a retrospective technique of comparing the performance of 'templating' using a hand-scoring method versus the scoring achieved by Orthoview™.

The hand-scoring carried out was the actual assessment and determination of prosthetic size using traditional templating methods using X-Ray film and template overlay versus the template size suggested by Orthoview™. The outcome of the comparison was that Orthoview™ provides an accurate alternative to traditional templating methods.

Conclusions of the non-clinical tests

Using a digital templating system such as Orthoview™ avoids unnecessary hard copying and also provides other benefits such as the ability to save the templating outcome in the patients electronic record, the templates are never lost or damaged and are readily available anywhere on the PACS network.

Using Orthoview™ provides an alternative to traditional templating methods with similar accuracy and can be used to augment standard PACS functionality to provide the required orthopaedic preoperative planning functionality.

Comparison of Technological Characteristics		
Characteristic	Predicate Device	Orthoview™
Computer	PC Workstation.	PC compatible computer .
Availability of Device	Launched from within the eFilm Workstation™.	Can be configured to be launched from within a workstation environment or as a standalone PC application.
Source of images	Receive digital images from various sources.	Same.
Processing of Image	Scaling of image facility.	Same.
Superimposing digital Prosthetic Templates	Permits Overlay of template.	Same.
	Permits automatic scaling.	Same.
	Interactive positioning of Template.	Same.
	Interactive sizing of template.	Same.
	Permits Template rotation.	Same.
	Permits mechanical linking of prosthetic components.	Same.
	Provides templating support from prosthetic manufacturers.	Same.
Preoperative Planning	Permitted.	Same.
Patient Contact & Control of Life Sustaining Devices	None.	Same.
Human intervention for interpretation of images	Permits physician intervention.	Requires physician intervention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Omsbar Ltd.
% Ms. Pamela Gwynn
Principal Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709

Re: K032401
Trade/Device Name: Orthoview™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 16, 2003
Received: August 4, 2003

Dear Ms. Gwynn:

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 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

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Indications for Use

Orthoview™ is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic devices, for the purposes of choosing the nature and characteristics of the prosthetic device to be used when planning a potential surgical procedure.

Prescription Use ✓

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032401