K052963

DEC 6 2005

7 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

1. Identification of Submitter:

Submitter:	Clario Medical Imaging, Inc.
Address:	725 N. State Street Bellingham, WA 98225
Phone:	360-312-5200
Fax:	360-312-5201
Contact:	Patricia A. Milbank
Title:	Regulatory Consultant
Phone:	425-894-9733
Fax:	425-865-9023
Date Prepared:	October 15, 2005

2. Identification of Product:

Trade Name:	MedIQ Version 1.0
Common Name:	Picture Archiving and Communications System
Regulation Number:	21 CFR 892.2050
Classification Name:	Image Processing System
Product Code:	LLZ
Manufacturer:	Clario Medical Imaging, Inc. 725 N. State Street Bellingham, WA 98225

3. Marketed Devices

MedIQ Version 1.0 is substantially equivalent to the legally marketed predicate devices listed below:

Model:	SharpView
Manufacturer:	ContextVision
510 (k) Number:	K993082
Model:	Vitrea 2, Version 3.7
Manufacturer:	Vital Images
510 (k) Number:	K043333

Model:	FuncTool 2000, designed for Advantage Workstation
Manufacturer:	GE Medical Systems
510 (k) Number:	K960265
Model:	MIStar
Manufacturer:	Apollo Medical Imaging Technology Pty. Ltd.
510 (k) Number:	K043350
Model:	Syngo Colonography Software Package
Manufacturer:	Siemens Medical Systems
510 (k) Number:	K030982
Model:	Realtime 3D Software Package
Manufacturer:	Siemens Medical Systems
510 (k) Number:	K973010
Model:	Fly Through PACS Software
Manufacturer:	Siemens Medical Systems
510 (k) Number:	K971717

4. Device Description:

MedIQ Version 1.0 is a software package designed to assist the radiologist in interpretation of multi-modality, digital radiology images, including dynamic CT and MR image data sets. The software applies standard 2D and 3D image processing techniques on a pixel-by-pixel basis to analyze grayscale data and perform visual enhancement of user-selected images. The software may be applied to image subtractions, reformatted images, multiplanar reformats, and maximum intensity projections. Single or multi-slice data sets may be used as input.

The results of the analysis are displayed as a surface map that enhances visualization of pixel intensity data provided by the image. The results may be displayed in grayscale enhancement or as a color overlay. The software includes standard workflow tools that allow the radiologist to manipulate, rotate and fly-though images for enhanced visualization of the digital output.

The software application consists of proprietary software developed by Clario and is a Windows 2000/XP, DICOM-compatible platform. The software is designed to be distributed as an SDK or as an application for installation on DICOM-compatible OEM imaging systems, PACS, workstations, stand-alone PCs, or embedded in software applications cleared for use in medical imaging. The device also may be distributed by Clario as a stand-alone PC product.

The MedIQ user interface is designed to follow typical clinical workflow patterns to process, review, and analyze digital images.

5. Indications for Use

MedIQ is a post-processing, productivity software package designed to assist radiologists in the analysis of dynamic CT and MR images. The software provides supplemental information and visual enhancement of time/intensity changes extracted from CT and MR temporal datasets. Single or multi-slice datasets, using standard acquisition protocols, are used for input.

The software displays the temporal variation in dynamic data as a surface map that enhances visualization of pixel intensity and time/intensity changes extracted from CT and MR temporal data sets. The results may be displayed as either a grayscale enhancement or a color overlay on the selected image.

MedIQ also may be used to perform post-processing analysis of multi-modality, digital images, including MR, CT, X-Ray, PET and Nuclear Medicine images. The software analysis tools may be applied to image subtractions, reformatted images, multiplanar reformats, and maximum intensity projections.

The software package includes tools to allow the radiologist to manipulate and fly-through images for enhanced visualization, and a z-axis kinematic motion feature.

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made based solely on the results of MedIQ analysis. The MedIQ software is not intended for use for primary interpretation of digital mammography images.

6. Comparison with Predicate Devices

MedIQ and the cited predicate devices are designed to assist radiologists in analyzing pixel intensity data from multi-modality, digital images and performing post-processing analysis of selected images using standard software techniques. The output of these software packages is intended to provide supplemental information and enhanced visual analysis of the digital images selected by the user for processing.

The GE FuncTool 2000 and MIStar software products perform post-processing analysis of dynamic CT and/or MR images to enhance the radiologist's visual interpretation of time/intensity changes observed in temporal data sets obtained during the administration of contrast agents. The output is displayed as curves or color parametric images from user-specified processing of algorithms.

The Siemens software packages, including Syngo, Realtime 3D, and Fly Through, provide functional features that are equivalent to MedIQ, allowing the user to view and manipulate images in 3D in real time, to make measurements on images and to provide 3D surface shading of selected images.

The cited predicate devices allow easy selection, review, processing, archiving, printing and media interchange of multi-modality images from a variety of diagnostic imaging systems.

7. Conclusions

MedIQ Version 1.0 provides functionality that is substantially equivalent to the cited predicate software devices. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. There are no new safety issues raised by this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2005

Ms. Patricia A. Milbank
Regulatory Consultant
Clario Medical Imaging, Inc.
725 N. State Street
BELLINGHAM WA 98225

Re: K052963
Trade/Device Name: MedIQ Version 1.0
Regulatory Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 18, 2005
Received: October 21, 2005

Dear Ms. Milbank:

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

K052963

6 Indication(s) for Use Statement

510(k) Number: To be assigned by FDA

Device Name: MedIQ Version 1.0

Indications for Use:

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The software displays the temporal variation in dynamic data as a surface map that enhances visualization of pixel intensity and time/intensity changes extracted from CT and MR temporal data sets. The results may be displayed as either a grayscale enhancement or a color overlay on the selected image.

MedIQ also may be used to perform post-processing analysis of multi-modality, digital images, including MR, CT, X-Ray, PET and Nuclear Medicine images. The software analysis tools may be applied to image subtractions, reformatted images, multiplanar reformats, and maximum intensity projections.

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Prescription Use ✓ 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)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052963