K093480

MAR - 5 2010

5 510(k) Summary

cuattro

510(k) summary

October 25, 2009

510(k) Owner

Cuattro, LLC

2946 Court Street

Pekin, IL 61554

Phone: 309-349-8901

Facsimile: 309-349-8902

510(k) Submitter

Mark Skeels

Cuattro, LLC

40 Bram Bay Road

Hopatcong, NJ 07843

Phone: 973-294-4363

Facsimile: 973-770-8486

Device Trade Name: Cuattro UnoMD

Common Name: System, Image Processing, Radiological

Classification Name: Picture archiving and communications system (21 CFR 892.2050, Product Code LLZ)

Substantial equivalence is claimed to the following Legally Marketed Device:

Manufacturer:	Del Medical Imaging
Device:	DEL-IMS
510(k) number:	K063188

Device Description

The Cuattro UnoMD software is a Windows based software application capable of acquiring x-ray images from commonly commercialized digital flat panels. The software can use traditional mouse and keyboard inputs as well as touch screen monitors as an alternative. The use of the software enables the user to use a separate traditional x-ray generator and capture x-ray images without film. The images are processed and then presented to the user on a touch screen computer monitor, within 12 seconds after the x-ray exposure. The software also has capabilities to send images to hospital medical PACS systems and digital media for archival.

Intended Use

The Cuattro UnoMD, when used with a cleared digital image capture device, provides for the capture of digital images in place of conventional film radiographic examinations. The device is intended to be available for retrofit on existing or planned x-ray machines with a cleared digital image capture device. The device is intended for use by trained and qualified personnel in the acquisition and review of radiographic images. The product is not intended for mammography or fluoroscopy applications.

Technological Characteristics

The technological characteristics are the same as the legally marketed predicate device, in that they provide a network connection via DICOM protocol to various devices from a radiographic system that utilizes a digital image capture device. The Cuattro UnoMD device is a software solution intended for use with already cleared digital image capture devices. The Cuattro UnoMD, as the predicate device, utilize software on a workstation computer with Ethernet capability, and provide DICOM 3.0 compliant connectivity.

Determination of Substantial Equivalence

The determination of substantial equivalence is based upon non-clinical performance data. Bench testing has been performed on the device following Cuattro's design control processes, as well as the applicable FDA guidance documents, in particular the guidance on Content of Premarket Submissions for Software Contained in Medical Devices. The results of this bench testing have demonstrated that the device is substantially equivalent to the referenced predicate device. **Note: Testing was performed utilizing the cleared digital image capture device, Samsung LTX240 (K090742).**

Conclusion

Based upon the analysis of the Intended Use, Technological Characteristics, and the results of the Bench Testing performed on the device, we have determined that the

Cuattro UnoMD is safe and effective, and substantially equivalent to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR - 5 2010

Cuattro LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K093480
Trade/Device Name: Cuattro UnoMD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 8, 2010
Received: February 16, 2010

Dear Mr. Job:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: _Cuattro UnoMD_____

Indications for Use:

The Cuattro UnoMD, when used with a cleared digital image capture device, provides for the capture of digital images in place of conventional film radiographic examinations.

The device is intended to be available for retrofit on existing or planned x-ray machines with a cleared digital image capture device.

The device is intended for use by trained and qualified personnel in the acquisition and review of radiographic images. The product is not intended for mammography or fluoroscopy applications.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093480

Page __ of __