K063037

510(k) Summary

OCT 18 2006

Per Title 21 CFR 807.92, and in accordance with the provisions of the SMDA 1990, CentarisOne, LLC is providing a summary of the safety and effectiveness information regarding the CentarisOne RIS/PACS system.

Date Prepared

August 26, 2006

Submitters Information:

CentarisOne, LLC
11925 Wilshire Blvd., Suite 301
Los Angeles, Ca. 90025
Establishment Registration: REGISTRATION_NUMBER
Contact: Scott Shannon, Product Director
(888) 747-2002 ext. 114 (phone)
(866) 816-2437 (fax)

Device Name:

Proprietary Name:	CentarisOne™ RIS/PACS
Common Name:	Picture Archiving and Communication System (PACS)
Product Code:	LLZ
Device Classification:	Class II – 892.2050
Classification Name:	System, Image Processing, Radiological

Predicate Device:

The CentarisOne™ RIS/PACS system is substantially equivalent to the:

Manufacturer:	Intuitive Imaging Informatics, LLC
Device:	IMAGEQUBE PACS
510(k) Number:	K051037
Decision Date:	06/28/2005
Decision:	Substantially Equivalent
Product Code:	LLZ
Device Classification Name:	System, Image Processing, Radiological
Device Classification:	Class II – 892.2050

Device Description:

The CentarisOne™ RIS/PACS is a comprehensive DICOM and IHE compliant radiology software based solution for small to mid-sized imaging centers. The RIS maintains control over all patient related information. The product integrates the imaging aspect with the front office details of the imaging center. It provides all users of the system with more information about the activities of a patient. This all leads to a smoother workflow and better patient care. The PACS component manages the image storage and image display to end-users while

tightly integrated into the radiology information system (RIS) to provide users with more patient information resulting in a tighter work-flow.

Indications for Use:

CentarisOne™ RIS/PACS is intended for use by a physicians and other medical staff as a full service DICOM and IHE compliant RIS/PACS solution for the storage, distribution and display of medical images from various imaging sources such as CT, MRI, NM, PT, DR, CR, US, XA scanners and secondary capture devices (film digitizers, etc.). This device may be used to archive mammography images (MG) but is not intended for primary diagnostic viewing of mammography images by this device.

Substantial Equivalence to Predicate Device:

There are no significant differences between CentarisOne RIS/PACS and IMAGEQUBE PACS device. Both devices provide a comparable set of features for image storage, communication and display. Both devices support standard DICOM protocol for communication of images with other medical imaging devices.

Technology Characteristics:

The device does not come in contact with the patient and does not control any life sustaining devices. The PACS device only stores and displays DICOM images to physicians and other professional clinical staff. The application software is designed, developed and tested using written procedures and quality controls.

Safety:

The device has been tested in non-clinical and clinical locations and proven to be safe and effective. The device contains instructions for use and warnings or cautions to provide for the safe and effective use of the device.

A risk and hazards analysis for the device is included with the 510(k) submission and the "Level of Concern" for potential hazards has been classified as "minor".

Conclusion:

The CentarisOne™ RIS/PACS product acquires, processes, archives and distributes images utilizing similar techniques functions and techniques as the predicate device IMAGEQUBE PACS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 18 2006

CentarisOne, LLC
c/o Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K063037
Trade/Device Name: CentarisOne™ RIS/PACS
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 2, 2006
Received: October 3, 2006

Dear Mr. Christensen:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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

Indications for Use

510(k) Number (if known): K063037

Device Name: CentarisOne RIS/PACS

Indications for Use:

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Prescription Use ✓
(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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063037