K06 3188

510 (k) Summary

NOV 3 0 2006

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:

Del Medical Imaging
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Contact Person:

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Date Prepared: October 17, 2006

Trade Name: DEL-IMS

Common Name: Operator Console and Imaging Workstation for Stationary Digital X-Ray Systems

Classification Name: 892.2050 Picture Archiving and Communications Device

Predicate Device: Sterling DROC, (K980970).

Product Description: The DEL-IMS is intended to provide a network connection via DICOM protocol to various output (e.g. hardcopy, softcopy and archive) devices from a radiographic system which uses a digital image capture device. It synchronizes the ready states of the digital image capture device and the radiographic equipment when a single x-ray console is desired, to provide the x-ray console features (e.g. technique selection) of the radiographic equipment.

Indication for Use: The DEL-IMS has application wherever the transmission of radiographic images and associated patient text data is desired to take place from an input, such as radiographic equipment which employs a digital image capture device, to an output device such as hardcopy, softcopy, or archive device.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Rationale for Substantial Equivalence: The DEL-IMS has the same indication for use as the predicate device. It shares the same technological characteristics as the predicate device. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device.

Safety and Effectiveness Information: The device labeling contains operating instructions for safe and effective use of the DEL-IMS. The software development for this device follows documented processes for software design, verification and validation testing. Final device validation and risk assessment will be completed prior to marketing, to identify potential design hazards that could cause an error or injury based on the use of this device. Appropriate steps will be taken to control all identified risks. The device will be tested for compliance to IEC 60601-1- 2 Medical Electrical Equipment Part 1: General Requirements for Safety.

Conclusion: The DEL-IMS performs the same functions in the same environment as the predict device (DROC). It is as safe and effective as the predict device. We believe it does not introduce any new potential safety risks and is substantially equivalent to the predict device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NOV 30 2006

Mr. William J. Engel
Manager, Quality Assurance/Regulatory Affairs
Del Medical Systems Group
11550 West King Street
FRANKLIN PARK IL 60131

Re: K063188
Trade/Device Name: DEL-IMS Digital Operator Console
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 17, 2006
Received: October 23, 2006

Dear Mr. Engel:

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

Indication for Use Statement

510k Number: (if known): K063188

Device Name: DEL-IMS Digital Operator Console

Indications for Use:

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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)

Prescription Use ✓ OR Over-The-Counter_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063188