K071241

510(k) Summary

Submitter's Information

JUN - 8 2007

Submitted by MEDIAN Technologies
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Date summary was prepared: May 14, 2007

Name of Device

Proprietary name: LMS-Liver
Common name: Image visualization and analysis software package
Classification Name: Class II 21 CFR 892.2050 LLZ

Predicate Devices

Manufacturer:	SIEMENS	CEDARA
Common Name:	Accessory to Computed Tomography X-ray System /II/ 90	Accessory to Computed Tomography X-ray System /II/ 90
Trade Name:	Syngo TrueD software	Cedara I-Response; Cedara PET/CT
510(k) Number:	K061671	K053301

Device Description

LMS-Liver is an image analysis software application for evaluating CT images covering the liver area. It is designed to assist radiologists in the evaluation and documentation of lesions. It also provides tools for assessment of lesion evolution over time. LMS-Liver offers measurement tools and 3D registration techniques for characterization and follow-up of the lesions. It also offers reporting capabilities making it possible to generate standardized reports. LMS-Liver can segment hepatic lesions identified by the user with a double click (seed point). Once a lesion is segmented, the software computes its characteristics such as size, volume and intensity.

LMS-Liver can match and compare lesions present in two different datasets of the same patient acquired at different dates and compute their difference of size and volume.

Indication for use

LMS-Liver is an image analysis software application for evaluating CT images covering the liver area. It is designed to assist radiologists in the evaluation and documentation of lesions. It also provides tools for assessment of lesion evolution over time. LMS-Liver offers measurement tools and 3D registration techniques for characterization and follow-up of the lesions. It also offers reporting capabilities making it possible to generate standardized reports.

LMS-Liver is intended to be used by radiologists and other clinicians qualified to interpret CT images.

LMS-Liver device is designed to be used with CT images covering the liver area in adult patients.

Substantial Equivalence Comparison Chart

Manufacturer	**Siemens**	**Cedara**	**MEDIAN**
Product Name	Syngo TrueD software	Cedara I-Response; Cedara PET/CT	LMS-Liver
510(k)	K061671	K053301	
Software only solution	√	√	√
Windows XP operating system	√	√	√
CT scans as Input	√	√	√
Support the oncological workflow by helping the user assess and document morphological changes in therapy follow-up examinations	√	√	√
Compare medical imaging data from different time points	√	√	√
Landmark matching and visual alignment	√	√	√
Lesion comparison over time	√	√	√
Report Generator	√	√	√

Safety

A comprehensive hazard analysis was carried out on MEDIAN Technologies' LMS-Liver software. It concluded that residual risks are acceptable when weighed against the intended benefits of the system.

Conclusion

LMS-Liver software does not raise new safety risks and is equivalent in function to existing legally marketed devices. LMS-Liver software is therefore substantially equivalent with respect to safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Median Technologies
% Mr. Chas Burr
President
Chas Burr Q/R Services, Inc.
11 Mystic Avenue
WINCHESTER MA 01890-2920

JUN - 8 2007

Re: K071241
Trade/Device Name: LMS-Liver
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 30, 2007
Received: May 3, 2007

Dear Mr. Burr:

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): _K071241__

Device Name: _LMS-Liver_____

Indications for Use:

LMS-Liver is an image analysis software application for evaluating CT images covering the liver area. It is designed to assist radiologists in the evaluation and documentation of lesions. It also provides tools for assessment of lesion evolution over time. LMS-Liver offers measurement tools and 3D registration techniques for characterization and follow-up of the lesions. It also offers reporting capabilities making it possible to generate standardized reports.

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071241