K033412

DEC 3 0 2003

Appendix E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Submitted by:

Name:	Medicsight PLC.
Address:	46 Berkeley Square London W1J 5AT UK
Telephone:	44 (0) 207 598 4070
Facsimile:	44 (0) 207 598 4071
Contact:	Carol MacDonald, RA QA Manager
Date of summary:	22 September 2003

Device Information:

Trade Name:	MedicLung™ Release 1
Common Name:	Medical imaging software for CT scanners
Classification Name:	Computed Tomography X-Ray System, Accessory
Regulation Number:	892.1750

Predicate Devices:

Medicsight MedicLung 1 is substantially equivalent to the following devices:

Manufacturer	Device	510(k) No.
GE	GE ADVANCED LUNG ANALYSIS-I	K013381
SIEMENS	LUNGCARE CT SOFTWARE PACKAGE	K022013

medicsight

K053412

Device Description:

MedicLung™ 1 is a software tool designed to assist radiologists and other clinicians in the evaluation of nodules and other lesions in the lug. The software allows the user to select Regions of Interest either manually or by selecting a single or double seed point, followed by semi-automatic detection of the ROI boundary. It provides 2D and 3D visualisation of nodules and other lesions, and measurement of nodule characteristics such as size and volume.

Intended Use:

MedicLung I is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the lung derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of lung lesions (e.g. nodules). The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting either a single or double seed point followed by interactive fine-tuning the boundaries of the ROI. MedicLung I provides quantative information for measurement of lesion volume and other measured characteristics over time allowing the user to review and track any changes in the physician-indicated nodules or lesions.

Comparison to Predicate Device:

As in the predicate devices, GE Advanced LungAnalysis-1 and Siemens LunCareCT, MedicLung 1 assists users in assessing CT images for the identification and evaluation of nodules and other lesions in the colon.

Test data are provided to validate the performance of the system and its substantial equivalence to the predicate devices. The functional features and the intended use of MedicLung 1 are substantially equivalent to the predicate devices.

Safety:

A comprehensive hazard analysis was carried out on MedicLung 1, which concluded that any residual risks were as low as reasonably practicable and judged as acceptable when weighed against the intended benefits of use of the system.

Conclusion:

MedicLung 1 does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. MedicLung 1 is therefore substantially equivalent with respect to safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

Ms. Carol MacDonald
Regulatory & Quality Director
Medicsight
46 Berkeley Square
London W1J5AT
UNITED KINGDOM

Re: K033412
Trade/Device Name: Medicsight MedicLung 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: OEB
Dated: October 24, 2003
Received: November 5, 2003

Dear Ms. MacDonald:

This letter corrects our substantially equivalent letter of December 30, 2003.

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 (PMA), 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX A

510(k) Number (if known): K033412

Device Name: Medicsight MedicLung 1.0

Indications for Use:

MedicLung I is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the lung derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of lung lesions (e.g. nodules). The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting either a single or double seed point followed by interactive fine-tuning the boundaries of the ROI. MedicLung I provides quantative information for measurement of lesion volume and other measured characteristics over time allowing the user to review and track any changes in the physician-indicated nodules or lesions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033412