5 510(k) Summary of Safety and Effectiveness

MAY 17 2011

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92(c).

5.1 Identification of Owner

Owner Name	Medicsight PLC
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Summary Date	November 18th, 2008

5.2 Identification of Product

Device Name	ColonCAD API
Device Common Name	Medical imaging software for CT scanners
Classification Name	Colon Computed Tomography System, Computer Aided Detection
Regulation Number	21 CFR 892.2050, Class II, NWE
Manufacturer	Medicsight PLC

5.3 Predicate Device

The predicate devices are:

- Colon CAR 1.2, Medicsight PLC (K042674)
- *syngo* Colonography package with extended functionality, Siemens Medical Solutions, Inc. (K042605).

5.4 Device Description

Medicsight ColonCAD API is a medical imaging software tool designed to assist radiologists in the detection of polyps in CT scans of the colon. The product is packaged as an Application Programming Interface (API) which allows it to be integrated into existing medical imaging solutions.

The ColonCAD API assists the radiologist in detecting colorectal polyps using mathematical image processing techniques. The CAD assists the radiologist by highlighting potential polyps in 2D and 3D image views. The results are displayed in the form of "CAD marks" on or near the potential polyps. The radiologist must assess every CT scan image to search for polyps and review the CAD marked images to determine if the indicated findings are polyps.

Patient management decisions should not be made solely on the results of ColonCAD analysis.

5.5 Indications for Use

Medicsight ColonCAD™ API is a non-invasive computer aided detection (CAD) image analysis software tool designed to assist radiologists in the detection of colorectal polyps during their review of digital images derived from CT colonography (CTC). This CAD software post-processes the CTC image data obtained from multi-detector computed tomography (MDCT) scanners.

The device is intended to be used on patients referred for a CT Colonography examination, as an overlay tool to prompt the radiologist to colonic findings that have

been identified by the device. The CAD can assist radiologists after they have made an initial review of all the CTC image data, supporting their evaluation ("second read").

5.6 Predicate Device Comparison

The ColonCAD API system and its predicate devices provide post-acquisition image analysis of CT colonography images which is used to assist the radiologist in the detection of colorectal polyps.

ColonCAD API is a modified version of its predicate Colon CAR Release 1.2, Medicsight PLC (K042674). The primary difference is the method of deployment. ColonCAD API is designed as an Application Programming Interface (API) thus enabling integration with other medical image visualization systems while Colon CAR Release 1.2 is designed as a stand-alone desktop application.

ColonCAD API is also substantially equivalent to "syngo - Colonography Package with Extended Functionality", Siemens (K042605).

Both predicate devices include tools which allow the enhancement of features in CT scans in order to assist the radiologist in the detection of colorectal polyps (Polyp Enhanced Viewing). ColonCAD API provides functionality which is substantially equivalent to these tools.

ColonCAD API has the same technological characteristics as the ColonCAR 1.2 predicate device. The ColonCAD API device uses the same underlying image processing technology as the ColonCAR 1.2 device to perform the post-processing analysis of CTC image data (i.e. it uses the same mathematical rationale, software architecture design, and code-base). The computer aided detection algorithm used in the ColonCAD API device is the same as the algorithm that was used in the ColonCAR 1.2 device. No additional features or functions were added to the ColonCAD API device except for the programming interface required to facilitate the display of the CAD marks on third party visualization systems.

Therefore, ColonCAD API is substantially equivalent to its predicate devices and does not introduce any new safety risks.

5.7 Performance Standards

No applicable FDA performance standards have been issued under the authority of Section 514.

ColonCAD API conforms to the DICOM Standard 3.0.

5.8 Summary of Studies

Medicsight has conducted non-clinical and clinical studies to verify, validate, and assess the performance of the ColonCAD API. Non-clinical studies include: functional testing, installation testing and internal clinical evaluations.

The intended use of ColonCAD API was validated in a clinical study. The results of the MRMC study demonstrated that radiologists' accuracy for detecting colorectal polyps of any size was significantly higher with CAD than in the unassisted read, as measured by the segment-level area under the ROC curve (AUC).

5.9 Conclusions

The intended use and technological characteristics of the ColonCAD API 3.1 device are similar to the predicate devices. Minor technological differences do not raise any new questions regarding the safety and effectiveness of the device. Thus, the ColonCAD API system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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MAY 17 2011

Re: K083423
Trade/Device Name: ColonCAD API
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: NWE
Dated: March 4, 2011
Received: March 7, 2011

Dear Ms. Gill:

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,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indication(s) for Use Statement

510(k) Number (if known): K083423

Device Name: ColonCAD API

Indications for Use:

Medicsight ColonCAD™ API is a non-invasive computer aided detection (CAD) image analysis software tool designed to assist radiologists in the detection of colorectal polyps during their review of digital images derived from CT colonography (CTC). This CAD software post-processes the CTC image data obtained from multi-detector computed tomography (MDCT) scanners.

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Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510K K083423