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5 510(k) Summary

As required by 21 CFR Part 807.87(h)

Submitter:	Kyle Peterson Director, Regulatory & Corporate Affairs Calgary Scientific Inc. Suite 208, 1210 - 20th Ave. SE Calgary, Alberta T2G 1M8 CANADA
Telephone Number:	(403) 767-7945
Fax Number:	(403) 270-2771
Name / Address of Manufacturer:	Calgary Scientific Inc. Suite 208, 1210 - 20th Ave. SE Calgary, Alberta T2G 1M8 CANADA
Date of Submission:	November 12, 2013

Identification of the Device

Device Proprietary Name:	ResolutionMD Mobile
Common Name:	Picture Archiving and Communication System
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II

Marketed Device to which Equivalence is claimed:

Device	Manufacturer	510(k) Number
ResolutionMD Mobile 3.1	Calgary Scientific Inc.	K123186
ResolutionMD Mobile	Calgary Scientific Inc.	K111346
Mobile MIM	MIM Software Inc.	K112930
Centricity PACS	GE Healthcare	K110875

Device Description:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and high-resolution Apple Inc. iOS and Google Inc. Android OS-based wireless mobile devices for the display and advanced visualization of medical image data. It provides for communication, storage, processing, rendering on the server and the display of DICOM 3.0 compliant image data on the mobile device.

Based on benchmark testing by radiologists comparing diagnostic confidence on the X-ray, ultrasound, PET and SPECT modalities on mobile devices with ResolutionMD Mobile to a predicate PACS workstation, this version amends the Indications for Use to include all DICOM 3.0 images.

Indications for Use:

ResolutionMD™ Mobile is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant medical images as well as reports on the mobile device.

ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

ResolutionMD Mobile is not to be used for mammography.

Technological Characteristics

The ResolutionMD™ Mobile software has the same technological characteristics as the predicate ResolutionMD Devices and has the same uses and applications as the predicate devices. Both the device and predicates are used by the clinician as a diagnostic, review, and analysis tool for radiological images.

Software Verification and Validation Testing

Verification testing consisting of more 160 separate tests, each executed multiple times by different testers, was performed for this device. Testing included functional, smoke and regression tests and was complemented by beta tests performed by Calgary Scientific's OEM distribution partners. The vast majority of tests passed our testing criteria. Any defects found or reported were either fixed or logged in the Unresolved Anomalies report included with this submission and annotated as to any impact on safety or effectiveness including applicable workarounds.

Validation testing based on typical clinical workflows was performed by trained radiology personnel. Validation includes usability assessment and consistency across three client platforms; Web, iOS and Android.

Performance Testing

Performance testing was conducted to qualify iOS and Android mobile devices, both smartphones and tablets, as devices whose off-the-shelf performance in combination with the overall attributes of the ResolutionMD Mobile solution provides acceptable image quality for diagnostic radiology.

The tests were performed in accordance with the description and requirements described in the AAPM Assessment of Display Performance for Medical Imaging Devices (2005) document by an ISO 17025-certified third party to ensure high quality laboratory results. The test equipment and calibration was certified traceable to NIST.

The specific results regarding the measured luminance from the mobile devices with respect to the target luminance response using JND plots was provided to the FDA as requested.

Clinical Testing

Clinical testing was conducted by a panel of nine board-certified radiologists in the United States. The radiologists conducted a side-by-side comparative assessment of the iOS and Android mobile devices running ResolutionMD Mobile with the predicate PACS workstation. A series of typical yet challenging X-ray, ultrasound, PET and SPECT cases were reviewed on each device. Comparative assessments of image quality and diagnostic confidence were made by each radiologist.

All nine radiologists agreed that the iOS and Android mobile devices, both smartphones and tablets, were either "equivalent" or "comparable" to the predicate PACS workstation across all four modalities and of adequate quality for clinical use. They were comfortable with the diagnoses made on the mobile devices using the ResolutionMD Mobile software. All agreed that the overall clinical image display quality on the iOS and Android devices was equivalent to the PACS workstation for the identification of clinically-relevant pathology.

All nine radiologists indicated that the software and devices provide acceptable quality for regular use and they were comfortable reviewing images on the devices.

For all the individual cases, there was agreement by all reviewers that the same diagnosis would be made on the mobile devices with ResolutionMD as on the predicate PACS workstation in office lighting conditions and in the low light conditions. None of the reviewers noted any differences in their perception of the images between the low light and office lighting conditions.

Safety and Effectiveness

The device is designed and manufactured under Quality System Regulations as outlined in 21 CFR 820. All requirements of Picture Archiving and Communications System (21 CFR 892.2050) are met, and software is in compliance with ISO 14971 and ISO 62304.

Substantial Equivalence:

Based on the above considerations, Calgary Scientific Inc. believes that the ResolutionMD Mobile software is substantially equivalent to the predicate devices. The device and the predicates are post-processing and provide the same or similar essential features of visualization of radiological data on mobile devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Calgary Scientific, Inc.
% Mr. Kyle Peterson
Director, Regulatory & Corporate Affairs
Suite 208, 1210 -20th Avenue SE
Calgary, Alberta T2G 1M8
CANADA

Re: K133508
Trade/Device Name: ResolutionMD Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 27, 2014
Received: March 6, 2014

Dear Mr. Peterson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE, Calgary, Alberta, CANADA T2G 1M8

510(k) Number: K133508

Device Name: ResolutionMD™ Mobile

Indications for Use:

ResolutionMD™ Mobile is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant medical images as well as reports on the mobile device.

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ResolutionMD Mobile is not to be used for mammography.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _ (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 Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K133508_____