

K123186

MAR 14 2013

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

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Name / Address of
Manufacturer: Calgary Scientific Inc.
Suite 208, 1210 - 20th Ave. SE
Calgary, Alberta
T2G 1M8
CANADA

Date of Submission: September 14, 2012

Identification of the Device

Device Proprietary Name: ResolutionMD Mobile 3.1

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:

<u>Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
ResolutionMD Mobile	Calgary Scientific Inc.	K111346

Device Description:

The ResolutionMD™ Mobile 3.1 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 derived from CT and MRI on the mobile device.

Indications for Use:

The ResolutionMD™ Mobile software 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 CT and MR medical images as well as reports on the mobile device.

The 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.

The ResolutionMD Mobile is not to be used for mammography.

Technological Characteristics

The ResolutionMD™ Mobile 3.1 software adds support for mobile devices running the Android operating system and has the same uses and applications as the predicate device. Both the device and predicate 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 than 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 (the subject of this submission and both phone and tablet devices).

Performance Testing

Performance testing was conducted to qualify an Android smartphone and an Android tablet 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.

Nine tests of display performance were conducted for each mobile device running ResolutionMD Mobile and both devices passed all of the tests.

Clinical Testing

Clinical testing was conducted by a panel of three board-certified radiologists in the United States. The radiologists conducted a side-by-side comparative assessment of the Android mobile devices running ResolutionMD Mobile with the predicate iOS devices. A series of typical CT and MR cases were reviewed on each device. Comparative assessments of image quality and diagnostic confidence were made by each radiologist.

All three radiologists agreed that the Android mobile devices, both the smartphone and tablet, were comparable to the predicate iPhone and iPad devices and of adequate quality for clinical use. They were comfortable with the diagnoses made on the Android mobile devices using the ResolutionMD Mobile software. All agreed that the overall clinical image display quality on the Android devices was equivalent to the iOS devices for the identification of clinically-relevant pathology. There were similar comments on image contrast and sharpness with comments including "very comparable" and "is diagnostic". No image artifacts were noted by the reviewers.

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

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 3.1 software is substantially equivalent to the predicate device. The device and the predicate are both post-processing and provide the same features of visualization of radiological data on mobile devices.



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

March 14, 2013

Kyle Peterson
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Re: K123186
Trade/Device Name: ResolutionMD™ Mobile 3.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 14, 2013
Received: February 19, 2013

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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: K123186

Device Name: ResolutionMD™ Mobile 3.1

Indications for Use:

The ResolutionMD™ Mobile software 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 CT and MR medical images as well as reports on the mobile device.

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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

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