DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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

APR 19 2012

Re: K120076
Trade/Device Name: ResolutionMD™ Web 2.9
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 19, 2012
Received: March 21, 2012

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.

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K120076

Device Name: ResolutionMD™ Web 2.9

Indications for Use:

The ResolutionMD(TM) is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

The ResolutionMD software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

ResolutionMD Web 2.9 is not to be used for mammography.

Prescription Use ___x___ (Part 21CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K1200276

Indications for Use

510(k) Number: K120076

Device Name: ResolutionMD™ Web 2.9

Indications for Use: Calcium Scoring module

The ResolutionMD(TM) is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

The ResolutionMD device incorporates a Calcium Scoring module which is used to identify and quantify calcified plaque within the coronary arteries. This protocol is performed on non-contrast enhanced cardiac CT data sets.

The ResolutionMD software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

ResolutionMD Web 2.9 is not to be used for mammography.

Prescription Use ___x___ (Part 21CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

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Evaluation and Safety

510(k) K1200276

Indications for Use

510(k) Number: K120076

Device Name: ResolutionMD™ Web 2.9

Indications for Use: Coronary Analysis module

The ResolutionMD(TM) is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

The ResolutionMD device incorporates a Coronary Analysis protocol which is used to visually identify and measure stenoses in the coronary arteries. This protocol is performed on contrast-enhanced cardiac CTA data sets.

The ResolutionMD software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

ResolutionMD Web 2.9 is not to be used for mammography.

Prescription Use ___x___ (Part 21CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) K1200276

Indications for Use

510(k) Number: K120076

Device Name: ResolutionMD™ Web 2.9

Indications for Use: Vessel Analysis module

ResolutionMD™ Web 2.9 is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

ResolutionMD Web 2.9 incorporates a Vessel Analysis module which is used as a post-processing diagnostic review and analysis application for images viewed from ResolutionMD™, a PACS workstation or DICOM image viewer. It is a tool for use by trained professionals such as physicians, technologists and surgeons to review, edit, analyze and report findings of vascular anatomy. Clinicians can semi-automatically determine contrasted lumen boundaries and stenosis measurements, and evaluate maximum and minimum lumen diameters and length measurements.

ResolutionMD Web 2.9 is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD Web 2.9 consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

ResolutionMD Web 2.9 is not to be used for mammography.

Prescription Use ___x___ (Part 21CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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