



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

August 24, 2016

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

Re: K161130

Trade/Device Name: ResolutionMD  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture Archiving and Communications System  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: July 22, 2016  
Received: July 26, 2016

Dear Kyle 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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read 'R. Ochs', is written over a faint, light-colored rectangular stamp or watermark.

For Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K161130

Device Name

ResolutionMD

Indications for Use (Describe)

Indications for Use Statement for ResolutionMD:

ResolutionMD® software is an enterprise medical image viewer used with off-the-shelf servers, web browsers, and specific mobile devices for the 2D display, Multi-planar reformatting and 3D visualization of medical image data and reports. It provides collaboration and integrated secure audio-video communication, and displays DICOM and non-DICOM medical images and reports.

ResolutionMD is intended for use as a diagnostic, review, and analysis tool by trained healthcare professionals to drive clinical management. When interpreted by a trained physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations.

ResolutionMD is not to be used for primary mammography diagnoses.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Indications for Use

510(k) Number (if known)  
K161130

Device Name  
ResolutionMD

### Indications for Use (Describe)

Indications for Use Statement for ResolutionMD with Vessel Analysis module:

ResolutionMD® software is an enterprise medical image viewer used with off-the-shelf servers, web browsers, and specific mobile devices for the 2D display, Multi-planar reformatting and 3D visualization of medical image data and reports. It provides collaboration and integrated secure audio-video communication, and displays DICOM and non-DICOM medical images and reports.

ResolutionMD incorporates a Vessel Analysis module which is used as a post-processing diagnostic review and analysis application for images viewed from ResolutionMD. It is a tool for use by trained healthcare professionals 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 is intended for use as a diagnostic, review, and analysis tool by trained healthcare professionals to drive clinical management. When interpreted by a trained physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations.

ResolutionMD is not to be used for primary mammography diagnoses.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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## 5 510(k) Summary

As required by 21 CFR Part 807.87(h)

### **Submitter**

Calgary Scientific Inc.  
Suite 208, 1210 - 20<sup>th</sup> Ave. SE, Calgary, Alberta, T2G 1M8  
CANADA

Phone: (403) 767-7945

Fax: (403) 270-2771

Contact person: Kyle Peterson, Director - Regulatory & Corporate Affairs

Date of Submission: April 19, 2016

### **Identification of the Device**

|                          |                                                                   |
|--------------------------|-------------------------------------------------------------------|
| Device Proprietary Name: | ResolutionMD®                                                     |
| Common Name:             | ResolutionMD                                                      |
| Classification Name:     | Picture Archiving and Communication System per<br>21 CFR 892.2050 |
| Product Code:            | LLZ                                                               |
| Device Class:            | Class II                                                          |

### **Marketed Device to which Equivalence is claimed**

| <i>Device</i>       | <i>Manufacturer</i>     | <i>510(k) Number</i> |
|---------------------|-------------------------|----------------------|
| ResolutionMD Mobile | Calgary Scientific Inc. | K133508              |
| ResolutionMD Web    | Calgary Scientific Inc. | K120076              |

### **Device Description**

ResolutionMD® software is an enterprise medical image viewer used with off-the-shelf servers, web browsers, and specific mobile devices for the 2D display, Multi-planar reformatting and 3D visualization of medical image data and reports. It provides collaboration and integrated secure audio-video communication, and displays DICOM and non-DICOM medical images and reports.

ResolutionMD incorporates a Vessel Analysis module which is used as a post-processing diagnostic review and analysis application for images viewed from ResolutionMD. It is a tool for use by trained healthcare professionals to review, edit, analyze and report findings of vascular anatomy.

### **Indications for Use**

*Indications for Use for ResolutionMD:*

ResolutionMD® software is an enterprise medical image viewer used with off-the-shelf servers, web browsers, and specific mobile devices for the 2D display, Multi-planar

reformatting and 3D visualization of medical image data and reports. It provides collaboration and integrated secure audio-video communication, and displays DICOM and non-DICOM medical images and reports.

ResolutionMD is intended for use as a diagnostic, review, and analysis tool by trained healthcare professionals to drive clinical management. When interpreted by a trained physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations.

ResolutionMD is not to be used for primary mammography diagnoses.

The Indications for Use Statement is a unification of the statements of the two previously cleared devices, along with the addition of some suggested wording from the IMDRF (International Medical Device Regulators Forum) guidance on SaMD (Software as a Medical Device) Risk Categorization. This unification is reflective of the similar architecture and device use case of the two cleared products. The intended use is the same between the three products and there are no new diagnostic claims involved in the wording change.

*Indications for Use for ResolutionMD with Vessel Analysis module:*

ResolutionMD® software is an enterprise medical image viewer used with off-the-shelf servers, web browsers, and specific mobile devices for the 2D display, Multi-planar reformatting and 3D visualization of medical image data and reports. It provides collaboration and integrated secure audio-video communication, and displays DICOM and non-DICOM medical images and reports.

ResolutionMD incorporates a Vessel Analysis module which is used as a post-processing diagnostic review and analysis application for images viewed from ResolutionMD. It is a tool for use by trained healthcare professionals 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 is intended for use as a diagnostic, review, and analysis tool by trained healthcare professionals to drive clinical management. When interpreted by a trained physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations.

ResolutionMD is not to be used for primary mammography diagnoses.

For the Indications for Use Statement for the Vessel Analysis module, the first and third paragraph is exactly the same as the Statement for the ResolutionMD device. The second paragraph, which contains the information specific to the Vessel Analysis module, is exactly the same as the previously cleared ResolutionMD Web with Vessel Analysis module.

**Technological Characteristics**

The ResolutionMD® 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 2000 separate tests, each executed multiple times by different testers, was performed for this device. Testing included functional, smoke and regression tests and was also complemented by beta tests performed by Calgary Scientific’s 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 all client platforms.

**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 “Medical devices – Application of risk management to medical devices” standard and IEC 62304 “Medical device software – Software life cycle processes” standard.

**Conclusion**

Based on the above considerations, Calgary Scientific Inc. believes that the ResolutionMD 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 web and mobile devices.