K06 2164

SEP 22 2006

5 510(k) Summary

Date Prepared:	July 21, 2006
Submitter's Name:	Calgary Scientific, Inc.
Submitter's Address:	1210 20th Ave. SE, Calgary, Alberta, Canada T2G 1M8
Submitter's Phone:	403.270.7159
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Contact:	Pierre Lemire, Chief Technology Officer
Proprietary Name:	ResolutionMD™
Common Name:	Software PACS
Classification:	892.2050 Picture archiving and communications system, Product Code LLZ, (Class II)
Substantially Equivalent to:	Tradename: Lucion Manufacturer: Mevisys 510(k) Number: K050033 Tradename: Plug 'n View 3D Manufacturer: Voxar Limited 510(k) Number: K992654 Tradename: Vitrea 2 Manufacturer: Vital Images, Inc. 510(k) Number: K032748

Device Description:

ResolutionMD™ 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, processing, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI. The ResolutionMD™ software takes advantage of dedicated graphics hardware to speed the creation 3D rendered images.

ResolutionMD™ is available in a Microsoft Windows version and in a Macintosh OS version. Both versions offer similar functionality. Available functions include DICOM communication, display of 2D images in original planes, computation and display of rendered 3D images and maximal intensity projection (MIP) images, and 2D and 3D image measurements. The user controls these functions with a system of interactive menus and tools.

The ResolutionMD™ software has been extensively tested on a variety of platforms by both members of the development and quality control team and by potential customers serving as beta testers. A hazard analysis has been conducted and the level of concern has been classified as minor. The release version of the software passed all tests considered critical in terms of patient safety and demonstrated an overall acceptable performance for release as determined by the predefined release criteria.

Substantial Equivalence Comparisons to Predicate Devices:

Feature	**ResolutionMD™**	**Mevisys Lucion™**	**Voxar Plug 'n View 3D™**	**Vital Vitrea 2™**
Computer Platform	Windows OS or Mac OS	Windows OS	Windows OS	Windows OS
DICOM compliance	DICOM 3.10	DICOM 3.0	DICOM 3.0	DICOM 3.0
2D Imaging	2D image viewer with interactive user controls	same	same	same
3D Imaging	3D volume rendering with interactive controls	same	same	same
Measurement	2D measurement tools	same	same	same
Maximum Intensity Projection (MIP)	MIP with interactive controls and clipping planes	same	same	same
Prescription Use	Yes	same	same	same
Intended Users	Trained Professionals	same	same	same

Intended Use:

ResolutionMD™ 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, processing, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

ResolutionMD™ 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.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Pierre Lemire
Chief Technology Officer
Calgary Scientific, Inc.
Suite 208-1210 20th Avenue SE
Calgary, Alberta, T2G 1M8
CANADA

SEP 22 2006

Re: K062164
Trade/Device Name: ResolutionMD™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 25, 2006
Received: July 28, 2006

Dear Mr. Lemire:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number (if known): K062164

Device Name: ResolutionMD™

Indications for Use:

ResolutionMD™ 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, processing, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062164