

Attachment D: 510(k) Summary

2062390

CRystalView® R200 Computed Radiography System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: Alara, Inc.
47505 Seabridge Drive
Fremont, CA 94538

Contact Person: Diane King
VP Regulatory Affairs
Phone: 510-315-5173
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Date Prepared: August 15, 2006

Trade Name: CRystalView® R200 Computed Radiography System

Common Name: Computed Radiography (CR) System

Classification Name: Solid State X-Ray Imager (per 21 CFR 892.1650)

Predicate Device: Alara CRystalView CR System 510(k)# K061538

Product Description:

The Alara CRystalView® R200 is a desktop Computed Radiography (CR) system designed to generate digital x-ray images by reading photostimulable phosphor image plates exposed using standard X-ray systems and techniques. The system consists of a CR Reader, a QC Workstation with software, cassettes, and image plates. Image data is sent via a dedicated connection from the Reader to the CRystalView R200 QC Workstation, where it is processed and displayed for review. The system outputs images and patient information to a PACS using the standard DICOM 3.0 protocol. The fully configured CRystalView R200 System includes acquisition console software and post-processing image enhancement software. A reseller may alternatively provide these two software components or appropriately cleared equivalents, as well as the QC Workstation hardware. The modification reported in this submission replaces the integrated third-party image enhancement software with image enhancement software developed by Alara.

Indications for Use:

CRystalView R200 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

Rationale for Substantial Equivalence:

CRystalView R200 with the Alara image enhancement software has the same indication for use as the unmodified predicate device. The Alara image enhancement software shares the same technological characteristics as the previously integrated third-party image enhancement software. However, the descriptive characteristics are not sufficiently precise to assure substantial equivalence. Therefore, Alara has carried out verification and image quality performance testing, including a confirmatory clinical concurrence study. The results of this testing demonstrate that the modified CRystalView with integrated Alara image enhancement software is substantially equivalent to the predicate CRystalView with integrated third-party image enhancement software.

Safety and Effectiveness Information:

CRystalView R200 is a Class II medical device and a Class I laser product. CRystalView R200 complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and laser safety of medical and/or laser devices.

Alara has performed laboratory and clinical studies to demonstrate that the modified CRystalView R200 performance characteristics and diagnostic capabilities are equivalent to the predicate. The results of these studies show that the modified CRystalView R200 performance characteristics are comparable with those of the predicate device. Clinically, no statistically significant difference was found in image quality ratings from CRystalView images processed with the predicate third-party image enhancement software and with Alara image enhancement software when images were judged by a radiologist.

Conclusion:

CRystalView performance tests and clinical studies have demonstrated that the modified CRystalView R200 incorporating Alara image enhancement software is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 18 2006

Ms. Diane King
Vice President Regulatory Affairs
Alara, Inc.
47505 Seabridge Drive
FREMONT CA 94538

Re: K062390
Trade/Device Name: Alara CrystalView® R200 Computed Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 15, 2006
Received: August 22, 2006

Dear Ms. King:

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.



Protecting and Promoting Public Health

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment B: Indications for Use Statement

510(k) Number: K062390

Device Name: Alara CRystalView® R200 Computed Radiography System

Indications for Use: CRystalView R200 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062390