

K071682



AUG 15 2007

**E. 510(k) Summary Statement**

**CRystalView T-Series 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

Registration Number: 2953719

Contact Person: Robert Lundberg  
Director of Regulatory Affairs and Quality Systems  
Phone: 510-315-5189  
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Date Prepared: July 18, 2007

Trade Name: CRystalView® T-Series Computed Radiography System

Common Name: Computed Radiography (CR) System

Classification Name: Solid State X-Ray Imager  
Class II, 21CFR 892.1650

Product Code: 90-MQB

Predicate Device: K042023: Fuji Computed Radiography (FCR) ClearView CS  
Image Reader (CR-IR363)  
K955643: DenOptix ALARA Imaging System

Product Description:

The CRystalView T-Series System is an electrostatic X-ray imaging system that employs storage phosphor plates in place of conventional X-ray film for radiographic imaging applications. The system provides image data that must then be viewed with an external computer and appropriate software. The CRystalView T-Series System is comprised of the following functional components: Reusable storage phosphor plates, multiple sizes; Plate carousels, corresponding to reusable storage phosphor plate size; The CRystalView T-Series Scanner, an image reader /digitizer. The CRystalView T-Series Scanner / Communications Interface, USB 2.0; Optional Integrated phosphor plate eraser;

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CRystalView T-Series control software and a user or distribution channel-supplied computer system. Image data is sent via a dedicated connection from the CRystalView T-Series Scanner to the computer system, where it is processed and displayed for review.

Indications for Use:

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

The CRystalView T-Series is not indicated for use in mammography.

Rationale for Substantial Equivalence:

The CRystalView T-Series is the equivalent of the DenOptix Imaging System. Its “Intended Use” statement limits the DenOptix Imaging System to dental computed radiography. The Fuji Computed Radiography (FCR) ClearView CS Image Reader uses the same ST-VI Imaging Plates for general computed radiography that is the same “Intended Use” desired for the CRystalView T-Series. Differences between the FCR ClearView and the present device are in the implementation of similar technologies for computed radiography. These differences do not alter the intended diagnostic effect of a computed radiographic imaging system.

Safety and Effectiveness Information:

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

Alara’s laboratory and V&V testing demonstrate that the CRystalView T-Series performance characteristics and diagnostic capabilities are equivalent to the predicate.

Conclusion:

The CRystalView T-Series’ performance is substantially equivalent to the DenOptix Imaging System and the FCR ClearView using the ST-VI imaging plates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

AUG 15 2007

Mr. Robert Lundberg  
Director, Regulatory Affairs & Quality Systems  
Alara, Inc.  
47505 Seabridge Drive  
FREMONT CA 94538

Re: K071682

Trade/Device Name: CRystalView® T-Series Computed Radiography System  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system  
Regulatory Class: II  
Product Code: MQB  
Dated: July 18, 2007  
Received: July 20, 2007

Dear Mr. Lundberg:

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.

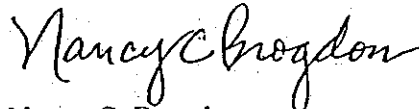
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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

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**C. Indications for Use Statement**

510(k) Number: **K071682**

Device Name: CRystalView<sup>®</sup> T-Series Computed Radiography System

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

The CRystalView T-Series is not indicated for use in mammography.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

JWhang 8/15/07  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K071682