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510(k) Summary

510(k) Number K08

Almana Medical Imaging
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JUN 20 2008

Date Prepared: February 11, 2007

Contact: Mohammed Irfanullah Farooqui,
Sales and Marketing Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: DR Vision Neo and DR Vision Duo Diagnostic X-Ray Systems
   Classification Name: Stationary x-ray system, Product Codes 90 KPR and MQB
   Common/Usual Name: Stationary Diagnostic X-Ray

2. **Equivalent legally marketed device:** K061054 Siemens Axiom Aristos FX Plus Digital Radiography System (uses identical digital panel).

3. **Indications for Use** (intended use) These are Radiographic X-Ray Systems with a flat panel detector(s), which allow the acquisition of x-ray exposures without the use of conventional film/screen systems. The systems allow radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying positions..

4. **Description of the Device:** DR Vision Neo is flat panel state-of-art digital imaging suite, driving significant improvements in productivity and quality. The streamlined efficiency of the DR Vision Neo enhance the entire radiographic operation, improving workflow by delivering diagnostic images instantly, and allowing users to move x-ray images electronically to remote workstations, image archives, and printers. The DR Vision Neo is a Trixell Pixium 4600 flat panel detector based direct digital radiography system with ceiling suspended design. These are essentially standard diagnostic x-ray systems which have added to them a digital x-ray acquisition panel. The DR Vision Neo has a single panel while the DR Vision Duo has two panels, one in a wall stand and one in the patient table. Features are:
   * Flat panel detector: Amorphous silicon panel with cesium iodide scintillator offers exceptional DQE 17" x 17" size eliminates the need to rotate the panel for transverse views 143 x 143 micron pixels in matrix of 3121 x 3121 x 14 bits. * High-precision 9 million pixel resolution. * 14-bit digital data conversion with 16,000 grayscales. * Motorized detector panel movements with auto-tracking with ceiling suspended tube stand. * Battery operated mobile elevating table for radiological applications with 4-way floating table top allows easy and quick patient positioning. * IHE/HL-7/DICOM Standard

5. **Safety and Effectiveness, comparison to predicate device**. The results of bench, test laboratory and clinical testing indicates that the new device is as safe and effective as the predicate devices.

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6. Substantial Equivalence Chart

Characteristic	K061054 Siemens Axiom Aristos FX Plus	DR Vision Neo and DR Vision Duo
Intended Use:	A dedicated x-ray system with a flat panel detector, which allows the acquisition of x-ray exposures without the use of conventional film/screen systems. The AXIOM Aristos FX Plus allows radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying positions.	These are Radiographic X-Ray Systems with a flat panel detector(s), which allow the acquisition of x-ray exposures without the use of conventional film/screen systems. The systems allow radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying positions.
Performance Standard	21 CFR 1020.30	SAME
Power range	50 Kw or 80 Kw	32-80 Kw
Digital Panel	Trixell 4600	Identical
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. Conclusion

After analyzing both bench and user testing data as well as external laboratory testing to applicable standards, it is the conclusion of Almana Medical Imaging that the DR Vision Neo and DR Vision Duo Diagnostic X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Almana Medical Imaging
% Mr. Daniel Kamm, P.E.
Regulatory Engineer, Submission Correspondnet
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K080614
Trade/Device Name: DR Vision Neo and DR Vision Duo Diagnostic X-Ray Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 27, 2008
Received: May 30, 2008

Dear Mr. Kamm:

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

510(k) Number (if known): K080614

Device Name: DR Vision Neo and DR Vision Duo Diagnostic X-Ray Systems

Indications For Use:
These are Radiographic X-Ray Systems with a flat panel detector(s), which allow the acquisition of x-ray exposures without the use of conventional film/screen systems. The systems allow radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying positions.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K080614