K120477

APR - 9 2012

510(k) Summary

as required by 807.92

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

2. Submitter's Name and Address

Shigeyuki Kojima
Manager
Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Telephone: 81-42-589-8429
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3. Date of Submission

February 10, 2012

4. Device Trade Name

AeroSync for AeroDR SYSTEM

5. Common Name

Digital Radiography

6. Classification, Product Code

Class II, 90MQB and 90LLZ

7. Predicate Device

AeroDR SYSTEM, 510(k) number K102349

8. Indications for Use

The AeroSync for AeroDR SYSTEM is a software device that is used in conjunction with AeroDR SYSTEM. This device 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.
This device is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

9. Device Description

The AeroSync for AeroDR SYSTEM is a software device that is used in conjunction with our AeroDR SYSTEM, K102349. It adds minor change for our cleared AeroDR SYSTEM. It eliminates the need for an electrical connection between the AeroDR SYSTEM and X-ray generator. It can be detected X-ray irradiation without cables connected to X-ray generator.

10. Risk Analysis

The Risk Analysis for the AeroSync for AeroDR System (X-ray perception software) was conducted on the basis of ISO14971, "Medical devices – Application of risk management to medical devices". As a result of risk control measures, the risk associated with all of the identified hazards was reduced to an acceptable level or ALARP (As low as reasonably practicable).

Please refer to Section 13, Appendix-G

11. Compliance of Recognized Consensus Standard

In terms of Indications for use of this AeroSync for AeroDR SYSTEM, it has been tested and shown to meet the requirements of IEC 60601-1 and IEC 60601-1-2 as follows. Please refer to the Section 7, STANDARD DATA REPORTS FOR 510(k)s.

Safety standard: IEC60601-1 Ed.2 (1988) + A1 (1991)+A2(1995)

Electromagnetic Compatibility: IEC60601-1-2 Ed.3 (2007)

Besides, AeroSync for AeroDR SYSTEM includes RF wireless technologies (which customer can select), so that to ensure safety of device in case of wireless use, it also has been tested and shown to meet the requirements of FCC part15 Subpart C,E.

12. Substantial Equivalence to Predicate Device

The predicate devices of AeroSync for AeroDR SYSTEM is our AeroDR SYSTEM, K102349.

The proposed device is a minor changed system of our cleared AeroDR SYSTEM. It eliminates the need for an electrical connection between the AeroDR SYSTEM and X-ray generator.

A comparison of the Indications for Use, Configuration, Specifications and Principals of operation by this proposed device and the predicate device has shown in Section 9, Substantial Equivalence Comparison Table.

The result of the Section 9, above mentioned the Risk Analysis and the

Compliance of Recognized Consensus Standard showed that there is no new safety and efficacy issue of the proposed device. Also, the results of performance testing shows that the image quality of proposed device is equivalent to the predicate device. Please refer to the section 14 and 15 Performance Testing.

The AeroSync for AeroDR SYSTEM is substantially equivalent to AeroDR SYSTEM, 510(k) Number, K102349.

9. Conclusion

Comprehensively, we conclude that the AeroSync for AeroDR System has the same technological characteristics as the predicate device. This 510(k) has demonstrated substantial equivalence as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta Medical & Graphics, Inc.
% Mr. Ressell Munves
Consultant
Storch, Amini & Munves, P.C.
140 East 45th Street, 25th Floor Tow Grand Tower
NEW YORK NY 10017

APR - 9 2012

Re: K120477
Trade/Device Name: AeroSync for AeroDR SYSTEM
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 14, 2012
Received: February 16, 2012

Dear Mr. Munves:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) :

Device Name : AeroSync for AeroDR SYSTEM

Indications for Use:

The AeroSync for AeroDR SYSTEM is a software device that is used in conjunction with AeroDR SYSTEM. This device 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.
This device is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

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 In Vitro Diagnostic Devices (OIVD)

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) K120477