K123499

510(k) Summary

as required by 807.92

DEC 2 0 2012

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
Fax: 81-42-589-8053

3. Date of Submission

November 9, 2012

4. Device Trade Name

AeroPilot

5. Common Name

Picture Archiving Communications System

6. Classification, Product Code

Class Ⅱ, 90LLZ

7. Predicate Device

AeroDR SYSTEM, 510(k) number K102349
AeroSync for AeroDR SYSTEM, 510(k) number K102349
AeroDR SYSTEM with P-21, 510(k) number K113248
(Konica Minolta Digital Radiography system)

8. Indications for Use

AeroPilot is a software device that is used in conjunction with REGIUS Unitea Unitea to control Konica Minolta Digital Radiography 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 AeroPilot is a software device that is used in conjunction with our REGIUS Unitea, K071436, to control Konica Minolta Digital Radiography systems. The AeroPilot is the software designed to be installed in Off-the-shelf PC (operation console) which is one of component of REGIUS Unitea and works with Konica Minolta Digital Radiography systems to be an interface with X-ray generator or between REGIUS Unitea and the specified Konica Minolta Digital Radiography systems, and to acquire X-ray images like the specified Konica Minolta Digital Radiography systems do.

10. Risk Analysis

The Risk Analysis for the AeroPilot (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 the Section 13, Software, Appendix 13-G

11. Substantial Equivalence to Predicate Device

The predicate devices of AeroPilot is our Konica Minolta Digital Radiography systems (K102349, K120477, K113248).

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

The result of the Section 9, above mentioned the Risk Analysis showed that there is no new safety and efficacy issue of the proposed device. Also, the results of performance testing show that the image quality of proposed device is equivalent to the predicate device. Please refer to the section 15 and Section 14(as reference data)

Therefore, the function of AeroPilot is substantially equivalent to the specified function that AeroDR SYSTEMS have.

12. Conclusion

Comprehensively, we conclude that the AeroPilot has the same technological characteristics as the predicate devices. This 510(k) has demonstrated substantial equivalence as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Konica Minolta Medical & Graphic, Inc.
% Mr. Russell Munves
Storch, Amini & Munves, P.C.
Official Correspondent
140 East 45th Street, 25th floor Two Grand Tower
NEW YORK, NY 10017

Re: K123499
Trade/Device Name: AeroPilot
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified flouroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 9, 2012
Received: November 13, 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K123499

Device Name: Aero Pilot

Indications for Use:

AeroPilot is a software device that is used in conjunction with REGIUS Unitea to control Konica Minolta Digital Radiography systems. 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 __Yes___ 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* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

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