K101842

FEB - 4 2011

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

January 24, 2010

4. Device Trade Name

Picture Archiving and Communications System, Acies

5. Common Name

Picture Archiving and Communications System

6. Classification

Class Ⅱ, 21 CFR 892. 2050, Picture Archiving and Communications System

7. Product Code

90 LLZ

8. Predicate Device

HOLOGIC SecurView DX, K062107
KONICAMINOLTA REGIUS Unitea / ImagePilot, K071436

9. Description of Device

The Acies is the software that is intended to configure PACS (Picture Archiving and Communications System) using a normal Windows-based PC. The workstation on which this software is installed can be utilized as the server-client front-end PC with the function of the Image server and the Viewer to read the image stored in the server. In addition, it is capable to

read the image from the client PC through the network.

The Acies primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The Acies can process and display medical images from a variety of different modality systems. It also interfaces to various image storage and printing devices using DICOM or DICOM based interface standards.

Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

The system is also capable of displaying the diagnostic image on the display screen by receiving DICOM SR from FDA approved CAD (Computed Aided Detection) processor.

10. Indications for Use

The Acies is a software product. It is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications.
The Acies primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The Acies can process and display medical images from a variety of different modality systems. It also interfaces to various image storage and printing devices using DICOM or similar interface standards.
Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

11. Substantial Equivalence to Predicate Device

As a PACS, the indication for use of the Acies is similar to HOLOGIC SecurView DX, K062107. Indications for use except mammography image display capabilities of the Acies is the almost the same to our REGIUS Unitea / ImagePilot, K071436.
Compare the Acies to above 2 devices in Section 4, Device Description, Comparison Table at Page 4-11 and 4-12 in detail. And, technological characteristics of the new device (Acies) and the predicate device are almost the same because hardware configuration, software function (ex:image processing) and expected connecting modalities are almost the same as our REGIUS Unitea / ImagePilot, K071436 and HOLOGIC

SecurView DX, K062107. The results of Verification and Validation testing shows that there is no safety and efficacy issue of the Acies introducing those already have identified with the predicate device.
The Acies is comparable and substantially equivalent to HOLOGIC SecurView DX, K062107 and is comparable and substantially equivalent to the capabilities excluding mammography image display capabilities of our REGIUS Unitea / ImagePilot, K071436.

12. Conformance to Standards

The Acies conforms to the following voluntary standards:

- IEC 62304:2006 Medical devices Software –Software life cycle processes
- ISO 14971:2007 Medical devices –Application of risk management to medical devices
- ISO/IEC 10918-1(1994-02): Digital Compression and Coding of Continuous-Tone Still Images(JPEG)
- DICOM(Digital Imaging and Communication in Medicine)

Detailed information of each refers to the following

- IEC 62304: Section 6,(Page6-7) and Appendix6-A
- ISO 14971: Section5
- ISO/IEC 10918-1(1994-02): Appendix4-C
- DICOM: Appendix4-A and 4-B

13. Conclusion

The Acies has basically the same technological characteristic as the predicate devices which are cleared 510(k) number K062107 and K071436. 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 Room – WO66-G609
Silver Spring, MD 20993-0002

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

FEB - 4 2011

Re: K101842
Trade/Device Name: Acies
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 24, 2011
Received: January 25, 2011

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,

Mary S Pastel

Mary Pastel, ScD.
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) : K101842

Device Name : Acies

Indications for Use:

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Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

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)~~ ODD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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