K082243

Name and Address of Sponsor

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Establishment Registration Numbers

8020997

Name and Address of Official Correspondent

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Truth and Accuracy Statement

Refer to **Appendix A.**

510(k) Statement

Refer to **Appendix B.**

Device Name

Proprietary Name: Precision RXi Analog X-ray System and PRECISION RXi Digital X-ray System

Common Name: Image-intensified fluoroscopic x-ray system, Solid state x-ray imager (flat panel/digital imager).

Classification Name: Image-intensified fluoroscopic x-ray system, Solid state x-ray imager (flat panel/digital imager).

Classification, Panel and Product Code

Class II, Radiology, OWB, JAA, 121

Previous Submission

The PRECISION RXi System was originally cleared by the FDA under 510(k) K041605

Indications for Use

The PRECISION RXi Analog X-ray System and PRECISION RXi Digital X-ray System are indicated for performing general R&F, radiography, fluoroscopy, interventional and angiography procedures/applications.

Please refer to the separate Indications for Use Statement contained in **Appendix C.**

Description of Design Changes

Intelligent Tilting

Positioner tilting / elevating movement will be modified as follows:

1 When the table top is longitudinally moved, the tilting command should also drive table top longitudinal movement to drive it back to center before tilting.

2 To ease scanning, when the tube is at the end of travel, continuing to push the tube joystick should drive longitudinal movement of the table top (at the current speed of table top).

3 When the positioner gets in interdiction movement (due to room constraints such as low ceiling), enable SID automatic movement back when table is tilted back to horizontal position (this shall be possible after stop of tilting movement and consequent movement back of SID).

4 When 16" I.I. is elevated and table top moved down (below 60mm) and command for cassette out is pushed, enable automatic elevating movement and only when enough room for I.I. movement down is created, the cassette out movement will be activated.

Compressor

This modification frees the patient from the compressor by means of a simple lever and a minimum effort by the operator when the Unit is in power OFF and the compressor is on the patient.

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

General Medical Merate S.P.A.
% Kevin Walls, RAC
Principal Consultant
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JUL 30 2012

Re: K082243
Trade/Device Name: PRECISION RXi Analog X-ray System and
PRECISION RXi Digital X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IZI
Dated: August 6, 2008
Received: August 11, 2008

Dear Mr. Walls:

This letter corrects our substantially equivalent letter of November 7, 2008.

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): K082243

Device Name:

Indications for Use: The PRECISION RXi Analog X-ray System and PRECISION RXi Digital X-ray System are indicated for performing general R&F, radiography, fluoroscopy, interventional and angiography procedures/applications.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082243