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NORDISK RØNTGEN TEKNI

K033486

510(K) Summary of Safety and Effectiveness

As required by section 807.92

Date Prepared:	October 3, 2003
Applicant:	NRT - Nordisk Roentgen Teknik A/S Quality Assurance Specialist Jan Malling
Address:	Birkegaardsvej 16 DK-8361 Hasselager DENMARK
Contact:	Tel.no. +45 8628 3500 Fax no. +45 8628 3088 Email: nrt@nrtxray.com
Device name:	GE Precision MPi
Common name:	Universal tilt-C
Classification:	Class II, sec.21CFR892.1650, Radiology, Image-intensified fluoroscopic x-ray system
Product code:	JAA, DWB

Legally marketed device to which we claim equivalence:
Philips MultiDiagnost 4, 510(K) no. K961374.

Device Description:
The GE Precision MPi tilt-C consists of an X-ray Generator, Right or Left side suspended Angulations Table with X-ray Tube, Collimator and Image Intensifier, Operators console, and Digital Imaging/Archive system.

Intended Use:
The GE Precision MPi is an all-digital multipurpose tilt-C X-ray system, intended for a multitude of diagnostic procedures, including: R&F, radiology, fluoroscopy, interventional procedures, vascular and non-vascular procedures, and specialized applications including angiographic studies

Summary of technological differences
There are no technological differences between the GE Precision MPi and The MultiDiagnost 4. Many of the components used are currently available and have been chosen for the GE Precision MPi to ensure proven effectiveness and safety.

Conformance:
The GE Precision MPi will conform to the applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL60601-1, IEC60601-1 and applicable collateral and particular standards.

Conclusion:
We believe that the GE Precision MPi is substantially equivalent to the Philips MultiDiagnost 4. The GE Precision MPi and the Philips MultiDiagnost 4 is intended for the same type of clinical use and for the same group of users. The GE Precision MPi does not introduce any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NRT-Nordisk Roentgen Teknik A/S
% Mr. Heinz-Jörg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
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MAY - 7 2012

Re: K033486
Trade/Device Name: GE Precision MPi
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: October 31, 2003
Received: November 4, 2003

Dear Mr. Steneberg:

This letter corrects our substantially equivalent letter of November 19, 2003.

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): K033486

Device Name: GE PRECISION MPi

Indications For Use:

The GE Precision MPi is a multi-purpose system that can perform general R&F, radiography, fluoroscopy, interventional and angiography procedures/applications.

Prescription Use ✓ 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033486