



K061028
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510(k) Summary

JUN - 7 2006

This 510(k) summary is prepared in accordance with the requirements of 21 CFR Part 807.87(h) and Part 807.92.

(1) Identification of Submitter:

Submitter: GE Healthcare
Address: 3000 N. Grandview Blvd. Waukesha, WI 53118
Tel: (262) 544-3894
Contact Person: Larry A. Kroger, Ph.D. (Senior Regulatory Programs Manager)
Summary Prepared: 04/10/2006

(2) Information of Device:

GE Model Name: Precision THUNIS 800+
Generic Name: Stationary Diagnostic Radiographic and Fluoroscopic X-ray System (Remote)
Classification Name: Image-intensified fluoroscopic x-ray system (21CFR § 892.1650)
Device Class: Class II
Product Code: JAA

(3) Predicate Device:

510(k) Number: K943805
GE Model Name: Prestige V, VH & VHD
Generic Name: Stationary Diagnostic Radiographic and Fluoroscopic X-ray System (Remote)
Classification Name: Image-intensified fluoroscopic x-ray system (21CFR § 892.1650)
Device Class: Class II
Product Code: JAA

(4) Device Description and Specification

Precision THUNIS 800+ is a Radiographic and Fluoroscopic system which consists of a tilting patient support table with both local and remote motion controls, a High-Voltage generator, a touch screen X-ray control console in control room (protected area), a X-ray tube assembly, a beam limiting device, a 9" inch Image Intensifier with Charge Coupled Device (CCD) video Camera, a removable 14"X17" film cassette tray, a Power Distribution Unit for whole system, an integrated control console including a workstation, Image Display, remote controls of tilting patient support table, collimator controls, spot film control and Fluoroscopic exposure control.

An in-room image display and in-room Fluoroscopic control foot switch are provided as an option for certain procedure which may need local X-ray loading and imaging.

No traditional spot film device using a film changer is provided with this system, spot-film image acquisition is fulfilled through digital image frame grabber and video camera.

For an illustration of the whole system and detailed product structure, please refer to SECTION 11 titled "Device Description".

(5) Statement of Intended Use

The Precision THUNIS 800+ is a digital remote R&F system intended to generate fluoroscopic and spot-film images of the patient during diagnostic procedures.

The system is indicated also for use in generating radiographic images of human anatomy in general purpose diagnostic procedures.

The system is not intended for mammographic or dental applications.

See SECTION 4 for a formal declaration of "Indications for Use".

See SECTION 12 for a comparison of Intended uses with the identified predicate device.

(6) Technological Characteristics Comparison

Precision THUNIS 800+ uses the same technological characteristics as the predicate device. Below is a brief summary.

Design: Precision THUNIS 800+ use the same X-ray imaging technology, same kind of film-screen cassettes for Radiographic applications, same kind of video camera (Charge Coupled Device) and Image Intensifier for Fluoroscopic applications.

Material: All construction materials are compliant with latest UL60601-1:2003 and applicable IEC60601 series standards which are comparable with the old UL 187 and IEC standards.

Chemical Composition:

Chemical composition of materials is not critical for this kind of device, because no material is implanted or inserted into the patient body or orifice to contact body tissues or fluids. Patient contact is not required for proper functioning of the device. See SECTION 15 for a statement of patient support tabletop material.

Energy Source: Precision THUNIS 800+ system uses the same kind of energy source as its predicate device: 3-Phase Mains Supply with Grounding, rated voltages can be set as any one of 380/400/415/440/480Vac, 50/60Hz.

Conclusions:

GE Healthcare considers the Precision THUNIS 800+ to be substantially equivalent to the identified predicate device which has the same indications for use and meets the similar standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN -7 2006

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems, LLC
3000 N. Grandview Blvd. W-440
WAUKESHA WI 53188

Re: K061028
Trade/Device Name: Precision THUNIS 800+
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: April 10, 2006
Received: April 13, 2006

Dear Dr. Kroger:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



Protecting and Promoting Public Health

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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Indications For Use Statement

510(k) Number (if known):

K061028

Device Name:

Precision THUNIS 800+

Indications for Use:

The Precision THUNIS 800+ is a digital remote R&F system intended to generate fluoroscopic and spot-film images of the patient during diagnostic procedures. The system is indicated also for use in generating radiographic images of human anatomy in general purpose diagnostic procedures. The system is not intended for mammographic or dental applications.

Prescription Use (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brodson

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

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