K011624

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GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201 USA

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Pat 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: 19 February, 2001

Identification of Product: Expedio 500D Radiographic and Fluoroscopic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53118

Device Description: The Expedio 500D R&F X-ray System consists of an X-ray generator; angulating table with X-ray Tube, collimator and image intensifier; Wall stand; Overhead tube suspension; Operator Console; and Digital Archive system.

Indications for Use: The Expedio 500D is designed to perform radiographic and fluoroscopic x-ray examinations.

Comparison with: The Expedio 500D R&F X-ray System is substantially equivalent to the Advantx Radiographic System (Originally cleared as the SCX K862120), InfiMed Patriot (K963037) and the Legacy/Legacy D Table (K973039).

Conformance: The Expedio 500D R&F X-ray System will conform to applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL 2601-1, IEC 601-1, IEC 601-1-2, and IEC 601-1-3.

Conclusions:

In the opinion of GE Medical Systems, the Expedio 500D R&F X-ray System is substantially equivalent to the presently marketed Advantx Legacy/Legacy D R&F X-ray System (K862120 and K973039) and the InfiMed Patriot Digital System (K963037). The Expedio 500D does not include any new indications for use, nor does use of this device result in any new potential hazards.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

GE Medical Systems
% Mr. Reiner Krumme
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTON CT 06470

Re: K011624
Expedio 500D R&F X-Ray System
Dated: May 22, 2001
Received: May 25, 2001
Regulatory Class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

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

Enclosure (s)

Attachment 1b

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510(k) Number (if known): K011624

Device Name:_____

Indications For Use:

The Expedio 500 R is designed to perform radiographic and fluoroscopic x-ray examinations

(see 510(K) Summary of safety and Effectiveness, attachment 1 of submission)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Jayne

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011624