K974367

FEB 13 1998

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 is submitted in accordance with the requirements of 21CFR part 807.87(h).

Identification of Submitter

Larry A. Kroger, Ph.D.
Senior Manager of Regulatory Programs
Telephone: (414)544-3894
Date Prepared: October 31, 1997

Identification of the Product

Name:	Advantx LCN+ angiographic imaging system
Manufacturer:	GE Medical Systems - Europe 283, rue de la Miniere 78533 Buc Cedex, FRANCE
Distributed by:	GE Medical Systems, Milwaukee, WI

Marketing History

The Advantx LCN+ x-ray angiographic system is substantially equivalent to currently marketed angiographic imaging systems that comply with the same or equivalent standards and have the same intended uses.

Device Descriptions

The Advantx LCN+ angiographic imaging system is an angiographic and radiographic biplane positioner for use with the x-ray system Advantx. It consists of an angiographic biplane positioner, a vascular table and an x-ray system.

Materials:	All construction and materials are compliant with UL 187.
Design:	There are hardware and software redundancies to prevent single point failures that could cause unintended motion.
Energy Source:	220 V AC 50/60 Hz

Indications for Use

The Advantx LCN+ angiographic imaging system is intended for general purpose diagnostic angiographic fluoroscopy and radiography study.

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510(K) SUMMARY OF SAFETY and EFFECTIVENESS

Adverse Effects on Health

The potential hazards (unintended emission of x-rays, excessive radiation, mechanical and electrical hazards) are identified in a Risk Management Summary and controlled by:

- Failure Mode and Effects Analysis (FMEA) to demonstrate the non-existence or extremely low probability of unwanted events.
- System evaluation to insure performance to specification and Federal Regulations.
- Adherence to Industrial Standards (UL)

Conclusions

The Advantx LCN+ angiographic imaging system complies with 21CFR and UL 187. This system poses no added safety risk.

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Identification of Submitter

Larry A. Kroger, Ph.D.
Senior Manager of Regulatory Programs
Telephone: (414)544-3894
Date Prepared: October 31, 1997

Identification of the Product

Name: Advantx LCLP+ angiographic imaging system
Mfg.: GE Medical Systems - Europe
283, rue de la Miniere
78533 Buc Cedex, FRANCE

Marketing History

The Advantx LCLP+ x-ray angiographic system is substantially equivalent to currently marketed angiographic x-ray systems that comply with the same or equivalent standards and have the same intended uses.

Device Descriptions

The Advantx LCLP+ angiographic imaging system is an angiographic and cardiographic biplane positioner for use with the x-ray system Advantx. It consists of an angiographic biplane positioner, a vascular table and an x-ray system.

Materials: All construction and materials are compliant with UL 187.
Design: There are hardware and software redundancies to prevent single point failures that could cause unintended motion.
Energy Source: 220 V AC 50/60 Hz

Indications for Use

The Advantx LCLP+ angiographic imaging system is intended for general purpose diagnostic angiographic fluoroscopy and cardiography study.

GE Medical Systems

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

510(K) SUMMARY OF SAFETY and EFFECTIVENESS

Adverse Effects on Health

The potential hazards (unintended emission of x-rays, excessive radiation, mechanical and electrical hazards) are identified in a Risk Management Summary and controlled by:

- Failure Mode and Effects Analysis (FMEA) to demonstrate the non-existence or extremely low probability of unwanted events.
- System evaluation to insure performance to specification and Federal Regulations.
- Adherence to Industrial Standards (UL)

Conclusions

The Advantx LCLP+ angiographic imaging system complies with 21CFR and UL 187. This system poses no added safety risk.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

Larry A. Kroger, Ph.D.
Regulatory Affairs
Program Manager
GE Medical Systems, Inc.
P.O. Box 414
Milwaukee, WI 53201

Re: K974367
Advantx LCN+ & Advantx LCLP+
Dated: November 18, 1997
Received: November 20, 1997
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Dr. Kroger:

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 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 requirement, 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) 594-4613. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Advantx LCN+ and Advantx LCLP+ angiographic x-ray systems

Indications for Use

The Advantx LCN+ is a biplane x-ray system consisting of a floor mounted three-axis C-arm and a ceiling suspended C-arm that addresses all angiographic procedures that require a 32 cm Image Intensifier.

The Advantx LCLP+ is a biplane x-ray system consisting of a floor mounted three-axis C-arm and a ceiling suspended C-arm that addresses all angiographic procedures that require a 22 cm Image Intensifier.

(PLESE 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)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974367