

K960575



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GE Medical Systems

P.O. Box 414, W-657
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY & EFFECTIVENESS

8 February, 1996

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

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Product: Advantx LCV+
X-ray Imaging System
Manufactured by GE Medical Systems - Europe, Buc, France
Distributed by GE Medical Systems, Milwaukee, WI

Indications for Use

The Advantx LCV+ x-ray imaging system is intended to be used for general purpose diagnostic angiographic fluoroscopy and radiographic studies.

Identification of the Product

Name: Advantx LCV+
Mfg: GE Medical Systems - Europe
238 Rue de la Miniere
78530 Buc, FRANCE

Indications for Use

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

Device Descriptions

The Advantx LCV+ imaging system is an angiographic and radiographic positioner with a 32 cm intensifier, for use with 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

Marketing History

In the opinion of GE Medical Systems, the LCA is of a comparable type and substantially equivalent to currently marketed diagnostic x-ray systems that comply with the same or equivalent standards and have the same intended uses.

Adverse Effects on Health

The potential hazards (unintended emission of x-rays, excessive radiation, mechanical and electrical) are identified in a Hazards Analysis 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

Use of the Advantx LCV+ imaging system does not result in any new potential safety risks.