K933447

AUG 23 1993

STENOSCOP 2

MOBILE X-RAY EQUIPMENT

APPENDIX A

SUMMARY OF SAFETY AND EFFECTIVENESS

K933447

510 (k) SUMMARIES OF SAFETY AND EFFECTIVENESS

IDENTIFICATION OF THE PRODUCT

NAME : STENOSCOP 2 Models 6000 & 9000
IMAGE INTENSIFIED C-ARM MOBILE FLUOROSCOPE

MFG. : GE MEDICAL SYSTEMS Benelux S. A.
Loncin ,Belgium

DISTRIBUTOR : GE MEDICAL SYSTEMS
Milwaukee - WI

INDICATIONS FOR USE :

The 6000 & 9000 series are C arm type Mobile Fluoroscopes , intended for use in Operating Rooms and other mobile applications .

DEVICE DESCRIPTION

The 6000 & 9000 series are the same as the present STENOSCOP 2-16 & 2-22 ,which consists of the following :

-X-ray generator and controller
-X-ray tube
-tube support
-image intensifier with video camera
-image storage and retrieval system ,and
-monitors

Materials : All construction and materials are compliant with UL 187 , and IEC 601-1 and 601-2-7 equipment standards .

Design : There are "hardware" redundancies to prevent single point failures (such as X-ray) .

Energy source : Single phase with ground .
The line voltage is set at the installation , and is one of the following :
100 - 108 - 120 - 200 - 208 - 220 - 228 - 240 V

Exposure levels : Fluoroscopy : 40 to 110 KV
0.1 to 6 mA
Radiographic : 40 to 110 KV
0.16 to 160 mAs

Features : *The C arm Mobile includes :
-X-ray generator and controls
-X-ray tube
-image intensifier and video camera
-X-ray tube and image intensifier support
*The Monitor Cart includes :
-TV monitors
-image storage and retrieval system
-video cassette recorder (option)
-thermal printer (option)
-film hard-copy camera (option)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Larry A. Kroger, Ph.D.
Correspondent
GE Medical Systems
General Electric Company
P.O. Box 414
MILWAUKEE WI 53201

NOV 21 2011

Re: K933447
Trade/Device Name: Stenoscop 2 Models 6000 and
9000 series Mobile
Fluoroscopic X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: July 12, 1993
Received: July 13, 1993

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of August 23, 1993.

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 (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. Please Note: CDRH does not evaluate information related to contact liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure