K980322

APR 24 1998

510(k) SUMMARIES OF SAFETY AND EFFECTIVENESS

IDENTIFICATION OF THE PRODUCT

NAME: ACCENT, MODELS 16 and 22
MOBILE X-RAY SYSTEM

MANUFACTURER: GE MEDICAL SYSTEMS - EUROPE
Loncin, Belgium

DISTRIBUTOR: GE MEDICAL SYSTEMS
Milwaukee, WI

INDICATIONS FOR USE:

The ACCENT systems are mobile image-intensified fluoroscopic x-ray systems, intended for use in general surgical procedures such as orthopedics, traumatology, visceral surgery, pacemaker implants, urology, etc. or other interventional procedures.

DEVICE DESCRIPTION

The ACCENT system is composed of:

a mobile C-Arm that includes:

- an image intensifier with CCD video camera
- an x-ray generator and controller
- an x-ray tube mounted in the same housing as the x-ray generator
- a beam-limiting device
- optional: a Laser beam alignment device
- optional: a dose area product meter and display

and a monitor cart that includes:

- TV monitors
- an image digital processing and storage system, may be of different models
- optional: VCR and video printers

Materials: All construction and materials are compliant with UL 2601-1, and IEC 601-1 equipment standards.

Design: The design meets or exceeds standards set forth in UL 2601-1 and IEC 601-1. There are hardware redundancies to prevent single point failures (such as x-ray emission and C-Arm motion)

Energy Source: Single phase, plus ground, 100 - 108 - 120 - 200 - 208 - 220 - 228 - 240 V, 50/60 Hz.
The supply voltage is set at the installation.

Exposure levels: Maximum rated peak tube potential: 110 kV
Fluoroscopic Entrance Exposure Rate (EER): less than 10 R/min.
Radiography: 160 mAs maximum, manual setting
Systems comply with the requirements of 21CFR 1020.30 - 31 - 32

Mechanical features: - mobile: forth and back, interlocked lateral travel
- C-Arm: forth and back, tilting (wig-wag), rotations

MARKETING HISTORY:

The ACCENT systems perform the same functions and replace the units listed below:

ACCENT 16:	STENOSCOP 2, Model 6000
ACCENT 22:	STENOSCOP 2, Model 9000

ADVERSE EFFECTS ON HEALTH:

The potential hazards (x-ray, mechanical and electrical) are controlled by compliance with the federal x-ray standard, adherence to industry standards (UL 2601-1) and warnings in the labeling.

CONCLUSIONS

The ACCENT systems are substantially equivalent to the above listed devices.
The energy source, exposure levels and principles of operation are very similar.
The changes to these Models do not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Mike Chilbert
Quality, Safety, & Regulatory Engineer
Technology & Product Assurance Group
GE Medical Systems
P.O. Box 414, W-709
MILWAUKEE WI 53201

NOV 17 2011

Re: K980322
Trade/Device Name: Accent 16 and 22 (Mobile X-ray System)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: January 22, 1998
Received: January 27, 1998

Dear Mr. Chilbert:

This letter corrects our substantially equivalent letter of April 24, 1998.

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

510(k) Number (if known): K980322

Device Name: Accent Mobile X-RAY System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980322

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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