



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

Mr. Jeff Wagner
Manager, Regulatory Affairs
GE OEC Medical Systems, Inc.
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

Re: K043076
Trade/Device Name: GE OEC Fluorostar
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified
fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: 90 JAA and IZL
Dated: October 28, 2004
Received: November 8, 2004

Dear Mr. Wagner:

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 application (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.

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 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); 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.

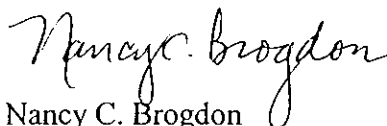
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

Indications For Use Statement

Applicant: GE OEC Medical Systems, Inc.

510(k) No. (if known):

Device name: OEC Fluorostar

Indications for use: The OEC Fluorostar is a mobile digital C-arm designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, stone localization, critical-care and emergency room procedures. The system may be used for other imaging applications at the physicians discretion.

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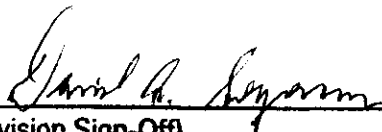
Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter ☐

(Optional Format 1-2-96)


(Division Sign-Off)Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K043076