



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

Mr. Milton D. Siegel
Manager, Medical Regulatory Affairs
Medical Group
Varian
611 Hansen Way
PALO ALTO CA 94303

JAN 12 2012

Re: K760429

Trade/Device Name: Fluoroscope, OEC/Varian Mobile
C-Arm Image Intensifier

Regulation Number: 21 CFR 892.1650

Regulation Name: Image-intensified Fluoroscopic x-ray system

Regulatory Class: II

Product Code: OXO

Dated: August 16, 1976

Received: August, 1982

Dear Mr. Siegel:

This letter corrects our substantially equivalent letter of August 16, 1976.

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

Dear Mobile Fluoroscopic Device Manufacture:

This letter is to advise you that the FDA is in the process of updating the Product Codes for Mobile Fluoroscopic (OXO) devices to provide greater specificity regarding Mobile X-Ray devices. Product Codes, and their definitions, can be found in our classification database (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm>).

Mobile X-Ray devices have expanded greatly in scope since the creation of the first Mobile X-Ray devices product code, IZL, over 30 years ago: from standard mobile radiographic systems to sophisticated mobile interventional fluoroscopy devices. Because of the variety of mobile X-Ray devices currently on the market, the new product code will allow FDA to distinguish between the different types of mobile S-Ray devices marketed in the United States (U.S.), thereby allowing us to serve the Medical Imaging device industry and other stakeholders in a more clear and efficient manner.

What you should do at this time:

When preparing import paperwork, including your FDA Listing, **you must** continue to reference the “Current Product Codes” that are found on your 510(k) letter of substantial equivalence to avoid delays at the port of entry into the U.S. Do **not** use the “Planned Common Name and Planned Product Code” on any FDA Submission until the codes have been finalized for your device, and you have been **notified by FDA by receipt of a revised letter of substantial equivalence for your 510(k)(s). (Attached)**

Need Further Clarifications?

If you need further clarification on the issue or any other type of assistance in complying with FDA regulations, please contact the Division of Small Manufactures, International and Consumer Assistance, (DSMICA), by email at DSMICA@CDRH.FDA.GOV

John Stigi
Director
Division of Small Manufactures, International and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
U.S. Food and Drug Administration



Memorandum

Date: December 1, 2011
From: Lauren Hefner
Subject: Regarding Product Code conversion from IZL to OXO
To: The Record

510(k) K760429, Fluoroscope, OEC/Varian Mobile C-Arm Image Intensifier was originally assigned a Product Code of IZL (892.1720, mobile x-ray system). As it is a fluoroscopic device it is being reassigned to the new Product Code of OXO (892.1650, image-intensified fluoroscopic x-ray system, mobile) to distinguish it from mobile radiographic x-ray systems.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
8757 Georgia Ave.
Silver Spring, MD. 20910
August 16, 1976

*received cdmib
8/82*

Mr. Milton D. Siegel, Manager
Medical Regulatory Affairs
Medical Group
Varian
611 Hansen Way
Palo Alto, California 94303

Ref: K760429-Fluoroscope, OEC/
Varian Mobile C-Arm Image
Intensifier

Dear Mr. Siegel:

Your Section 510(k) notification of intent to market the above device has been reviewed. We have determined, based on the information available to us at this time, that the device is substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the date of enactment of the Medical Device Amendments of 1976. You may, therefore, begin marketing of your device without waiting for the expiration of the 90-day notice period.

Upon marketing, your device will be subject to the general controls imposed by the Federal Food, Drug, and Cosmetic Act, which currently include requirements relating to annual registration with the Food and Drug Administration, adulteration, and misbranding. We will soon send you information about how to register with FDA. These current requirements may later be supplemented by regulations, which will be proposed for comment in the Federal Register, relating to current good manufacturing practices, records and reports, and other requirements. Upon final classification of the device, your product may be required to meet additional requirements applicable to Class II devices (performance standards) or Class III devices (premarket approval).

You should follow closely the classification proceedings conducted by the Food and Drug Administration so that you can convey your views to the Agency if you so desire, and so that you can promptly comply with any additional requirements subsequently imposed on your device. Information on meetings of the device classification panels, their recommendations, and the final decisions of the Agency will be published in the Federal Register. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, Maryland, 20852.

Sincerely yours,

David M. Link, Director
Bureau of Medical Devices
and Diagnostic Products

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K760429 – Medical Group

Final: CD 11.22.2011

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DRAO	HEFNER	12-1-11			
DRAO	O'Hara	12/1/11			