



Mr. James Lambrecht
Official Correspondent
Acoma Medical Imaging, Inc.
150 Chaddick Drive
WHEELING IL 60090

JAN 12 2012

Re: K893617
Trade/Device Name: MCA-501 Mobile C-Arm
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: May 9, 1989
Received: May 10, 1989

Dear Mr. Lambrecht:

This letter corrects our substantially equivalent letter of July 14, 1989.

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

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/cfpcd/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: November 30, 2011
From: Lauren Hefner
Subject: Regarding Product Code conversion from IZL to OXO
To: The Record

510(k) K893617, MCA-501 Mobile C-Arm 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.



JUL 14 1989

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910Acoma Medical Imaging, Inc.
Attn: James Lambrecht
150 Chaddick Drive
Wheeling, Illinois 60090Re: K893617
MCA-501 Mobile C-Arm
Dated: May 9, 1989
Received: May 10, 1989
Regulatory Class: II

Dear Mr. Lambrecht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K893617 – Acoma Medical Imaging, Inc.

Final: CD 11.30.2011

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DRA D	HEFNER	12-1-11			
DRA Q	Ottawa	12/1/11			