



Shimadzu Corporation  
% Mr. Randal Walker  
X-ray Tech Support Manager  
Shimadzu Medical Systems  
20101 South Vermont Avenue  
TORRANCE CA 90502-1328

NOV 14 2011

Re: K043379

Trade/Device Name: Surgical Mobile C-arm Imaging Z-ray System WHA-200  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system, mobile  
Regulatory Class: II  
Product Code: OXO  
Dated: November 22, 2004  
Received: December 30, 2004

Dear Mr. Walker:

This letter corrects our substantially equivalent letter of February 17, 2005.

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) Notification Submission, WHA-200

**SECTION XI: INDICATION FOR USE STATEMENT**

510(K) Number (if known): K043379  
~~Unknown~~

Device Name: WHA-200

**Indications for Use:**

- The device is a Surgical Mobile C-arm Imaging X-ray System and allows a technician to examine a patient by fluoroscopy or radiography.
- This device is operated and used by Physicians and X-ray technologist.
- The object of this device is total patient populations.

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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)

Prescription Use

OR

Over-The-Counter Use

(Per2I CFR801.109)

*[Signature]*  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K043379