JUN 19 2006

510(k) Summary

In accordance with the requirements of 21 CFR §807.92 the following summary of 510(k) safety and effectiveness information for the Ziehm Vision FD is being submitted.

Date:

April 26, 2006

Name of Submitter:

Ziehm Imaging, Inc.
4181 Latham Street
Riverside, CA 92501
(951) 718-2020

Corresponding Official:

Richard Westrich,
V.P. Product Development, Regulatory Affairs

Device Proprietary Name:

Ziehm Vision R Digital Mobile Imaging System

Classification Name:

System, X-ray, Fluoroscopic, Image-Intensified -or

System, X-ray, Mobile

Common/Usual Names:

Mobile C-arm,
Fluoroscopic Imaging System

Substantial Equivalence:

The ZIEHM VISION R is substantially equivalent to the following devices that are currently marketed:

- Ziehm Imaging, Inc. ZIEHM VISION Digital Mobile Imaging System 510(k) K011292
- OEC 9800 Plus Digital Mobile Imaging System 510(k) K021049
- OEC 9800 E/CV^{+} Digital Mobile Imaging System 510(k) K024012

These devices are mobile C-arm type x-ray systems intended for fluoroscopic imaging. The systems include high-voltage x-ray generator, and control, rotating and fixed anode x-ray tubes, image intensifier, and monitor cart/workstations with video image displays, digital image processing and image storage capability, as well as conventional spot-film capability.

Device Description:

Indications for Use

The Ziehm Vision R is designed to provide pulsed and continuous fluoroscopic imaging, and spot film imaging of the patient during diagnostic, Interventional and surgical procedures. The design includes features for diagnostic and interventional cardiac imaging procedures, and is also intended for use in visualizing complex anatomical structures and procedures for vascular, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, and critical care and emergency room procedures. At the discretion of physician the device may be used for other imaging applications.

Radiographic film examinations can be made with an accessory cassette device attached to the Image Intensifier.

User Characteristics

The device is intended for use by health care professionals such as physicians, surgeons, cardiologists, radiologists and technologists in hospitals, out-patient clinics and other clinical environments. Ziehm Imaging anticipates the device will be used on a nearly daily basis. Ziehm Imaging applications specialists and/or qualified site personnel provide on site operator training in the proper use of the device.

General Description

The Ziehm Vision R has two mobile units: a mobile C-arm stand and a monitor cart/ workstation. The C-arm stand contains the x-ray control, high voltage generator, VisionCenter touch control user interface, power subs-systems, and control system. The "C profile" or C-shaped mechanical assembly supports at one end the image intensifier and the other the high voltage generator and tube housing assembly. The C-Profile is designed to perform rotational and linear movements that allow the user to position the imaging components at various angles and distances with respect to the patient.

The monitor cart/workstation supports dual flat panel LCD display monitors, integrated Ziehm Vision digital image system, imaging capture, image processing, DICOM 3, and VisionCenter touch control user interface. External Video connection is provided with RS-170 video timing for domestic market, CCIR for International markets.

The Ziehm Vision R also provides optional peripheral connections for such devices as video printers, thermal printers, network connections, DICOM 3, and external media storage such as USB, DVD devices. A single auxiliary connection is provided for connection to angiographic injector systems with the aim of synchronizing image acquisition of angiographic images during contrast media injections.

Standards:

The ZIEHM VISION R series mobile x-ray systems were designed to comply with applicable portions of the following standards and regulations for product safety requirements:

- Federal Performance Standard for Diagnostic X-ray Systems 21 CFR 1020.30, 21 CFR 1020.31 and 21 CFR 1020.30
- UL 60601-1 Medical Electrical Equipment
- IEC 6060'1-1, Medical Electrical Equipment, General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility
- IEC 60601-1-3, Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-4, General requirements for safety, Programmable electrical medical systems.
- IEC 60601-2-7, Medical Electrical Equipment, Safety of HV/X-ray Generators
- IEC 60601-2-28, Medical Electronic, Particular Requirements for Safety of X-ray Source Assemblies, and X-ray Tube Assemblies.
- IEC 60601-2-32, Medical Electrical Equipment, Safety of Associated X-ray Equipment
- IEC 60825-1, Safety of Laser Products, Equipment Safety , Requirements, and User Guide
- 93/42/EEC - Annex 1 Essential Requirements of the Medical Devices Directive
- DIN ISO 14971

Conclusion:

The ZIEHM VISION R does not raise new questions of safety or effectiveness and is substantially equivalent to the current model Ziehm Vision K011292, and OEC 9800 Mobile C-arm K021049 and OEC 9800 E/CV^{+} K024012

End of 510(k) Summary

Richard Westrich
Vice President Product Development and Regulatory Affairs
Ziehm Imaging, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY 23 2012

Mr. Richard Westrich
Vice President of Product Development
and Regulatory Affairs
Ziehm Imaging, Inc.
4181 Latham Street
RIVERSIDE CA 92501

Re: K061203
Trade/Device Name: Ziehm Vision R
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and OXO
Dated: April 27, 2006
Received: May 1, 2006

Dear Mr. Westrich:

This letter corrects our substantially equivalent letter of November 14, 2011.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Applicant: Ziehm Imaging, Inc.

510(k) Number (if known): K061203

Device Name: Ziehm Vision R

Indications for Use: The Ziehm Vision R is designed to provide pulsed and continuous fluoroscopic imaging, and spot film imaging of the patient during diagnostic, Interventional and surgical procedures. The design includes features for diagnostic and interventional cardiac imaging procedures, and is also intended for use in visualizing complex anatomical structures and procedures for vascular, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, and critical care and emergency room procedures. At the physician's discretion the device may be used for other imaging applications.

Radiographic film examinations can be made with an accessory cassette device attached to the Image Intensifier.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061203