510(k) Summary

K061310

In accordance with the requirements of 21 CFR §807.92 the following summary of 510(k) safety and effectiveness information for the Ziehm Vario / 3D Family is being submitted.

Date:

April 29, 2006

JUL - 7 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 Vario 3D Mobile Imaging System

Classification Name:

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

System, X-ray, Mobile

Common/Usual Names:

Digital Mobile C-Arm,

Fluoroscopic imaging System,

Digital Mobile Imaging System

Substantial Equivalence:

The ZIEHM VARIO 3D is substantially equivalent to the following devices that are currently marketed:

- SIEMENS Medical Systems AG ISO-C 3D Mobile Surgical C-arm System 510(k) K003266
- SIEMENS Medical Solutions USA, ISO-C 3D Mobile C-arm System 510(k) K032280

These devices are mobile C-arm x-ray systems intended for fluoroscopic and 3d imaging. The systems include high-voltage x-ray generator and control, x-ray tube, image intensifier, and monitor cart/workstation, with video image displays, 2D and 3D digital image processing and image storage capability, Computer Aided Surgery (CAS) interface, as well as conventional spot-film capability.

Device Description:

Indications for Use K061310

The ZIEHM VARIO and ZIEHM VARIO 3-D C-arms provide fluoroscopic and spot film imaging of the patient during diagnostic, Interventional and surgical procedures. It is intended to be used whenever the Clinician benefits from Iso-centric positioning and/or intraoperatively generated 3D imaging of high contrast objects (bones and joints), complex anatomical structures such as cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities. The design includes features intended for performing vascular, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, and critical care and emergency room procedures. At the discretion of a 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 to be used by health care professionals such as physicians, surgeons, cardiologists, radiologists and technologists in hospitals, out-patient clinics and other clinical environments. It is expected that 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.

Device Description

The ZIEHM VARIO 3D has two main units; Mobile Stand and Monitor Cart workstation. The Mobile Stand C-arm consists of a high frequency generator, x-ray tube assembly, image intensifier, and user touch control interface, C-Profile supporting the generator and image intensifier and Integrated Laser light localizers in the image receptor. The Mobile Stand C-profile provides fixed distance mounting of the generator and image receptor allowing the user rotational and linear movements for positioning the c-arm at various angles and distances for visualization of patient's anatomical structures in addition the device has variable ISO Centric operation, and integrated Iso-centric operations for performing 3D imaging.

The monitor cart workstation supports dual flat panel LCD display monitors, digital image memory device, imaging capture, image processing, and touch control user interface. External Video connection is provided with RS-170 video timing for domestic market, CCIR for International markets. The ZIEHM VARIO 3D also provides optional peripheral connections for such devices as video printers, DICOM 3, CAS connection for image guided surgery and external media storage devices.

Standards: K061310

The ZIEHM VARIO 3D 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 VARIO 3D does not raise new questions of safety or effectiveness and is substantially equivalent to the current legally marketed devices SIEMENS ISO-C 3D K003266, and SIEMENS ISO-C 3D K032280.

End of 510(k) Summary

Richard Westrich
Vice President Product Development and Regulatory Affairs
Ziehm Imaging, Inc.
Riverside, CA 92501

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 7 2006

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

Re: K061310
Trade/Device Name: Ziehm Vario 3D
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: JAA and IZL
Dated: April 29, 2006
Received: May 10, 2006

Dear Mr. Westrich:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

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

Enclosure

ziehm imaging

Indications For Use Statement

Applicant: Ziehm Imaging, Inc.

510(k) Number (if known): K061310

Device Name: ZIEHM VARIO 3D

Indications for Use: The ZIEHM VARIO and ZIEHM VARIO 3-D C-arms provide fluoroscopic and spot film imaging of the patient during diagnostic, Interventional and surgical procedures. It is intended to be used whenever the Clinician benefits from Iso-centric positioning and/or intraoperatively generated 3D imaging of high contrast objects (bones and joints), complex anatomical structures such as cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities. The design includes features intended for performing vascular, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, and critical care and emergency room procedures. At the discretion of a 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.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061310