K092438

Appendix 7 - 510(k) Summary Ziehm Solo

DEC 23 2009

The following information is being submitted in accordance with the requirements of 21 CFR §807.92

Preparation Date: Dec 17, 2009

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

Contact Person:
Richard L. Westrich
Vice President of Regulatory Affairs and Quality Assurance
4181 Latham Street
Riverside, CA 92501
Office phone: +951-781-2020 ext 140
Fax: +951-781-6457

Device Trade Name: Ziehm Solo

Classification Name: 21 CFR 892.1650 System, X-Ray, Fluoroscopic, Image Intensifier,
Product Code: JAA

ommon/Usual Names:
Digital Mobile C-Arm
Mobile Surgical C-Arm
Mobile C-Arm

Predicate Device: ZIEHM VISION^2 K073346, 21CFR 892.1650, System, X-Ray, Fluoroscopic, Image Intensifier,
Product Code JAA, IZL

Device Description: The Ziehm Solo Mobile Stand incorporates a single arm monitor assembly providing a more adaptable positioning of the display monintors to the clinician and the C-arm in relation to the patient. The C-profile provides fixed distance mounting of the generator and Image Intensifier and manual rotation around a non iso-centric location. The mobile stand allows the manual rotational and linear movements of the C-arm with a motorized vertical movement for positioning the c-arm at various angles and distances for visualization of patient's anatomical structures. Optional 120kV and or 20mA Fluoro operations are available. The 2.02 kW high frequency generator incorporates a single focus fixed anode x-ray tube, and high voltage generator is a single mono-block generator tube housing assembly. The virtual collimator and x-ray control mount to the generator housing assemble and provides pulsed and continuous fluoroscopy operations including a special digital radiography (snapshot) mode. The SoloCenter is a centralized touch screen providing the user/operator with a graphical user Interface including the x-ray control panel. The Ziehm Solo does not have a conventional Monitor Cart, the workstation consists of a mechanical arm assembly supporting a single or dual high-resolution flat panel LCD display monitor(s). Ceiling or wall monitors can be added by means of two external monitor connectors. Other conventional external interfaces are provided on the mobile stand for preipherial devices such as video printers, and storage devices such as USB and DVD.

Indications of Use:

The Ziehm Solo is intended to provide contactless fluoroscopy Imaging, capturing, temporarily storing, and display of non-invasive x-ray imaging of the patient using pulsed and continuous fluoroscopy, during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room fluoroscopy procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. This device does not support and is not intended for use in performing mammographic imaging.

Contraindications to the use of X-rays:

The exposure of humans to ionizing radiation must always be medically justified. Especially when used on pregnant women, adolescents, children, and pediatric patients, all procedures using ionizing radiation should be used with caution or be avoided altogether. However, the final decision and responsibility lies with the attending physician or attending surgeon in deciding whether to use the system with such patients.

The system may only be used in heights up to 6561.7 ft (2000 m) above sea level and must be used within the limits defined by the technical specification. The use of the system is only allowed in rooms used for medical purposes in accordance 60601-1-2 with EMC class A as well as with protective earth conductor. The system may only be used in an environment with an oxygen saturation <25%. The system may only be used in faultless condition and in accordance with the terms set forth by the operating instructions.

Technology:

The Ziehm Solo Employs the same fundamental scientific technology as the predicate device.

User Characteristics:

The Ziehm Solo does not require nor is it intended to be used in contact with patients.
In some circumstances however, as part of its use in clinical environments the patient may come in contact with the device when operator moves or positions the device. The device is intended for use by health care professionals such as but not limited to physicians, orthopedic surgeons, vascular surgeons, neuro-vascular surgeons, radiologists, or other clinical physicians and technologists in hospitals, emergency rooms, 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.

Standards:

The Ziehm Solo mobile x-ray devices shall be tested and be shown to meet the appropriate requirements of the following standards prior to being marketed.

21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems
IEC 60601-1,	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 (FDA/CDRH Recognition Number 12-34: IEC 60601-2-7 (1998), Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators. (Radiology))
IEC 60601-2-28	Medical Electrical Equipment Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis
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
IEC 14971	Risk Management

Determination of Substantial Equivalence: The demonstration of substantial equivalence is based on a comparison of features to the predicate device and an assessment of non-clinical performance test data. Information is included with this submission that supports this determination.

Conclusion: The comparison table of the predicate device in Appendix 3 and the Performance testing, Clinical Evaluation Addendum, and Clinical Evaluation Ziehm Vision Family included in Appendix 5 demonstrates that the Ziehm Solo does not raise new questions of safety or effectiveness and performs in an equivalent manner to the predicate device and in accordance with its labeling.

End of 510(k) Summary

Richard L. Westrich
Vice President Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.
4181 Latham St.
Riverside, CA 92501

K092438

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 23 2009

Mr. Richard L. Westrich
V. P. Regulatory Affairs & Quality Assurance
Ziehm Imaging, Inc.
Division of Ziehm LLC (based in the USA)
4181 Latham Street
RIVERSIDE CA 92501

Re: K092438
Trade/Device Name: Ziehm Solo
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: October 29, 2009
Received: November 9, 2009

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 (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,

Janine M. Morris
Acting 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): K092438

Device Name: Ziehm Solo

Indications for Use:

The Ziehm Solo is intended to provide contactless fluoroscopy Imaging, capturing, temporarily storing, and display of non-invasive x-ray imaging of the patient using pulsed and continuous fluoroscopy, during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room fluoroscopy procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. This device does not support and is not intended for use in performing mammographic imaging.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092438

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