



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

Ziehm Imaging GmbH
% Mr. Richard L. Westrich
Director of Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.
6280 Hazeltine National Drive
ORLANDO FL 32822

October 6, 2016

Re: K161976
Trade/Device Name: Ziehm Solo FD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, OXO
Dated: July 15, 2016
Received: July 18, 2016

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. Please note: CDRH does not evaluate information related to contract 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161976

Device Name

Ziehm Solo FD

Indications for Use (Describe)

The Ziehm Solo FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides contactless fluoroscopic image capture, temporarily storing, and display of digital subtraction, and acquisition of cine loops during diagnostic, interventional and surgical procedures. Examples of clinical application may include pediatric, cholangiography, endoscopic, urologic, lithotripsy, orthopedic, neurologic, vascular, cardiac, angiographic, critical care, and emergency room fluoroscopy procedures.

The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications. This device does not support direct radiographic film exposures and is not intended for use in performing mammography.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Volume 005 510 (k) Summary

Sep 15, 2016

In accordance with 21 CFR §807.92 the following 510(k) summary information is provided:

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Device (Trade Name): Ziehm Solo FD
510(k) Number K161976
Common /Usual Names: Mobile Fluoroscopic C-Arm
Classification(s) 21CFR 892.1650
Classification Names: Image-intensified fluoroscopic x-ray system
Device: Interventional fluoroscopic x-ray system
Product Code: OWB, OXO, JAA

Predicate Device: Ziehm Solo (K092438)
Classification(s) 21CFR 892.1650
Classification Names: Image-intensified fluoroscopic x-ray system
Device: Interventional fluoroscopic x-ray system
Product Code: OWB, OXO, JAA

Predicate Device: Ziehm Vision² FD (K073346)
Classification(s) 21CFR 892.1650
Classification Names: Image-intensified fluoroscopic x-ray system
Device: Interventional fluoroscopic x-ray system
Product Code: OWB, JAA, JAK

General Description: The Ziehm Solo FD mobile fluoroscopy system is comprised of a mobile stand with a C-Profile shaped support with both a mono-block high voltage generator assembly and Flat Panel image receptor. These attach to either end of a C-Profile providing a fixed SID. The device performs 2D medical imaging using 4 axes of manual movement and one vertical axes of motorized movement. Additionally the device has the option of additional motorized axes of rotational movement for the C-profile (A-Axes / angulation). The optional motorization of the single A-axes provides the user an alternative for visualizing anatomical structures when performing certain procedures such as but not limited to working with lithotripsy procedures. A user touch screen provides for concise user selectable anatomical programs and X-ray technique control. Integrated high-resolution flat panel display monitors directly mounted on the horizontal arm of the mobile stand providing the clinician with a precise angle for visualization of live

fluoroscopic images of the patient's anatomy. This visualization helps to localize regions of pathology for surgical procedures. The mobile stand supports both a cable bound and optional wireless fluoroscopic footswitch. The Wireless footswitch operation allows for optimum positioning for the surgeon by removing the cable on the floor. The optional interface panel of the Ziehm Solo FD provides connection of peripheral devices such as external monitors, thermal video printers, and image storage devices (USB, DVD) and DICOM fixed wire and wireless network interfaces.

Indications for Use:

The Ziehm Solo FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides contactless fluoroscopic image capture, temporarily storing, and display of digital subtraction, and acquisition of cine loops during diagnostic, interventional and surgical procedures. Examples of clinical application may include pediatric, cholangiography, endoscopic, urologic, lithotripsy, orthopedic, neurologic, vascular, cardiac, angiographic, critical care, and emergency room fluoroscopy procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications. This device does not support direct radiographic film exposures and is not intended for use in performing mammography.

Summary of Technological Characteristics:

The comparisons of the predicate devices show the scientific and technology characteristics of the Ziehm Solo FD are substantial equivalence to that of the predicate devices.

Differences Features/Technology	Subject Device Ziehm Solo FD (K161976)	Predicate Device Ziehm Solo (K092438)	Predicate Device Ziehm Vision ² FD (K073346)
Mobile fluoroscopic c-arm	Yes	Yes	Yes
Product Codes	OWB, OXO, JAA	OWB, OXO, JAA	OWB, JAA, JAK

Classification	21CFR 892.1650	21CFR 892.1650	21CFR 892.1650
Mobile stand user touch control panel	Yes, same design	Yes, same design	Yes, same design
X-ray generator and tube housing assembly monoblock technology	Yes, same monoblock design, stationary anode tube	Yes, same monoblock design, stationary anode tube	Similar monoblock design, stationary anode tube
KV Range 40-110 kV	Yes	Yes	Yes
KV Optional Range 40-120 kV	Yes	Yes	No
Max power output	2.0 kW	2.0 kW	2.0 kW
2.4 kW has the ability to provide higher mA at lower kV levels allowing shorter pulse widths at variable frame rates to increase the image quality of moving objects by reducing or eliminating the movement during each single pulse.	Optional 2.4 kW	No	No
Collimator/beam limiter shutters	Yes, same design Asymmetric Slot	No, IRIS with Slot Collimator for circular image receptor	Yes, same design Asymmetric Slot
Pre Collimator	Square	Round	Square
Virtual collimation	Yes	Yes	Yes
X-ray Image Receptor	SSXI/CMOS 20.5 cm x 20.5 cm	I.I./cesium iodide Ø 23 cm or Ø 31 cm	SSXI/Amorphous silicon 20 cm x 20 cm
Flat Panel Detector (SSXI)	Yes	No	Yes
FPD FOV	Square FOV	Round FOV	Square FOV
Pixel Size	100_µm	N/A	194 µm
Detector Matrix	2,048 x 2,048 pixels	N/A	1,024 x 1,024 pixels
Camera Matrix	NA	1,024 x 1,024 pixels	NA
Grayscale:	16 bit (65,536 shades of gray)	12 bit (4,096 shades of gray)	16 bit (65,536 shades of gray)
Dynamic range	68 dB	N/A for image intensifier devices	94 dB
DQE	70 %	65 %	77_%
System resolution	4 lp/mm	5.2-6.8 lp/mm	2.4 lp/mm
ZAIP (Ziehm Adaptive Image Processing)	Adaptive noise filter adapts to the physical characteristics of the input signal	No, recursive noise filtering	Adaptive noise filter adapts to the physical characteristics of the input signal
Removable anti-scatter grid	Yes	Yes	No

AERC Dose control system	Similar design and control	Similar design and control	Similar design and control
Image Post Processing	Yes, same design	Yes, same design	Yes, same design
DICOM functionality including RSDR	Yes, same design	Yes, same design	Yes, same design
TFT Flat Screen Displays	Yes	Yes	Yes
Orbital movement	165°	135°	135°
SID	Geometry with new Flat Panel required 109 cm	95 cm	111 cm
Motorized Angulation	Yes, optional	Yes, optional	No
Option to dismantle the device in several modules	Variant "Portable"	Variant "Portable"	No
Monitor Cart	Optional "Viewing Station"	Optional "Viewing Station"	Mandatory Monitor Cart

Summary of Non-Clinical Test Data:

Ziehm Solo FD is based on the direct modifications to cleared predicate devices Ziehm Solo (K092438) and Ziehm Vision² FD (K073346); The design changes were completed in accordance with Ziehm Imaging GmbH Quality Management System Design Controls and Engineering, standards compliance, and Verification and Validation testing were successfully conducted on the Ziehm Solo FD. Further compliance testing for the modified device to all FDA requirements as stated in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" as applicable including software requirements and software risk hazards was done.

Tests performed on the Ziehm Solo FD, demonstrated that the device is safe and effective, performs comparably to the predicate devices, and substantially equivalent to the predicate devices.

Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken with the new device and the predicate device Ziehm Vision² FD (K073346). Documentation

provided in this submission demonstrates compliance of the modified device Ziehm Solo FD to all FDA requirements stated in "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components" as applicable. This includes but is not limited to leakage radiation of diagnostic source assembly, peak tube potential (kV), tube current mA, fluoroscopic entrance exposure rates, and beam-limiting alignment to device image receptor. Further, this performance testing confirmed that the Ziehm Solo FD complies with 21 CFR 1020.30-32 Federal Performance Standards for X-Ray Fluoroscopic equipment and with relevant voluntary safety standards for Electrical Safety and Electromagnetic Compatibility testing, specifically IEC standards listed in the table below.

With regard to the flat panel detector (SSXI), test documentation provided in this submission demonstrates compliance of the modified device Ziehm Solo FD to "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices". This includes but is not limited to DQE, resolution, image quality of comparative sets of images, dynamic range, beam alignment, dose rates, frame rate, geometry, and resolution to predicate device.

The verification/validation activities successfully confirmed device requirements have been fulfilled, system functionality is consistent with the user needs, intended uses, and the Ziehm Solo FD device correctly performs as designed, and raises no new questions regarding either safety or effectiveness.

Therefore, when compared to the predicate devices the Ziehm Solo FD supports a determination of substantial equivalence to the predicate devices.

Compliance Standards:

FDA/CDRH From 3626 (1/14)	"A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"
21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems.
MDD 93/42/EEC	Annex II of the European Medical Devices Directive (MDD) 93/42/EEC.
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

AAMI/ANSI ES60601-1	Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, mod) Date: 2010 Conformance Standard #19-5
IEC 60601-1	Medical Electrical Equipment, General Requirements for Safety Edition 3.0 (+Corr.1+Corr.2), Date: 2005-12-15
IEC 60601-1-2	Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility Edition 3.0, Date: 2007-03-30, Conformance Standard #19-1
IEC 60601-1-3	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment Edition 2.0, Date: 2008-01-22 Conformance Standard #12-210
IEC 60601-2-43	Medical electrical equipment, Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures Edition 2.0, Date: 2010-03-25 Conformance Standard #12-202
IEC 60601-2-54	Medical electrical equipment, Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy Edition 1.0, Date: 2009-06-29 Conformance Standard #12-274
IEC 60825-1	Safety of laser products, Equipment Safety, requirements, and user guide Edition 2.0, Date: 2007-03-30 Conformance Standard #12-273
ISO 14971	Medical devices - Application of risk management to medical devices Edition 2.0, Date: 2007-03-01 Conformance Standard #5-40

Conclusion: Ziehm Imaging GmbH considers the Ziehm Solo FD to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Vision² FD (K073346) and Ziehm Solo (K092438) in accordance with its labeling.

End of 510(k) Summary



Richard L. Westrich

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