December 12, 2023

Ziehm Imaging GmbH
℅ Tsvetelina Milanova
Specialist Regulatory Affairs
Lina-Ammon-Strasse 10
Nuremberg, Bavaria 90471
GERMANY

Re: K231669
Trade/Device Name: Ziehm Solo FD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: November 13, 2023
Received: November 14, 2023

Dear Tsvetelina Milanova:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K231669

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. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

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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December, 7 2023

In accordance with 21 CFR §807.92 the following 510(k) K231669 summary information is provided:

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US Agent	Kevin Bridgman VP Quality Assurance & Regulatory Affairs Ziehm-Orthoscan, Inc. 14555 N 82nd St Scottsdale AZ, 85260
Device (Trade Name):	Ziehm Solo FD
Common /Usual Names:	Mobile Fluoroscopic C-Arm
Regulation:	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system

Product Code:	OWB; JAA, OXO
Classification:	II
Predicate Device:	K161976 Ziehm Solo FD
Reference Device	K193230 Ziehm Vision FD
Decision Date:	10/06/2016
Regulation:	21CFR 892.1650
Regulation Description Name:	Image-intensified fluoroscopic x-ray system
Product Code:	OWB; JAA, OXO

Summary of Technological Characteristics

The Ziehm Solo FD uses X-ray imaging technology to visualize the human anatomy. The X-ray tube in the generator produces X-rays that penetrate the patient and then hit a special detector that converts them into digital images. This is done under the control of the user and at the direction of a physician who determines the specific clinical procedure. This visualization assists the physician in localizing pathological areas or during surgical procedures. The device enables real-time image acquisition as well as visualization of in vivo surgical procedures and post-operative results.

The Ziehm Solo FD consist of one mobile unit, the Mobile Stand. Optionally the device can be ordered with a Viewing Station (Monitor Cart). The Mobile Stand incorporates a small compact design making the positioning of the C-arm in relation to the patient easier for the operator. The generator with X-ray tube, advanced heat management system, X-ray control and collimators are assembled in one housing in a mono-block generator. The system control is handled via CAN BUS control system.

The mechanical C-Profile supports the generator, the flat panel detector and an integrated laser positioning device.
The optional available Viewing Station (Monitor Cart) provides a remote touch Solo Center that duplicates the touch Solo Center mounted on the Mobile Stand.

The proposed modified device Ziehm Solo FD employs the same fundamental control, and substantially equivalent scientific technology as that of our predicate device Ziehm Solo FD (K161976). Software architecture design is substantially equivalent to that of the predicate Ziehm Solo FD

The primary modification of the C-Arm includes an 8 inch IGZO (Indium gallium zinc oxide) flat panel detector (FPD The new 8 inch IGZO FPD is an addition to already introduced CMOS FPD. The flat panel detectors have the same outer product design of the housing, both devices use safety shielding

for radiation suppression and use solid state x-ray image receptors (SSXI / FPD) 8 inch CMOS and the only difference to the predicate Ziehm Solo FD is the additional 8 inch IGZO panel.

The comparison of the predicate device and the modified devices shows that the scientific and technical characteristics of the Ziehm Solo FD are substantially equivalent as those of the Ziehm Solo FD predicate device (K161976).

Intended Use

The Ziehm Solo FD is a mobile C-arm providing image data by means of a non-invasive x-ray technique during medical procedures and stores them temporarily. The Ziehm Solo FD is intended for use in all medical indications requiring fluoroscopy. The system is intended for use with human beings of any age. It is the physician's responsibility to decide whether to use the system with infants, children, and adipose patients. The system is intended for use with human bodies covering such structures but not limited to the following, e.g., organs, tissue, bones, implants depending on the medical indication.

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. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

Device Comparison Table

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Model	**Modified Ziehm Solo FD**	**Predicate *Ziehm Solo FD (K161976)***	**Comparable Properties Substantial Equivalence Discussion**
510(k) Number	K231669	K161976	---
Product Codes	OWB (interventional fluoroscopic x-ray system) Subsequent: JAA (system, x-ray, fluoroscopic,	OWB (interventional fluoroscopic x-ray system) Subsequent: JAA (system, x-ray, fluoroscopic,	Identical

Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
	image-intensified), OXO (image-intensified fluoroscopic x-ray system, mobile)	image-intensified), OXO (image-intensified fluoroscopic x-ray system, mobile)	
Device Image/ General Overview			The flat panel detectors are identical in the design of the housing, both devices use safety shielding for radiation suppression and use solid state x-ray image receptor (SSXI / FPD) 8 inch CMOS and the only difference to the predicate Ziehm Solo FD is the new 8 inch IGZO FPD.

Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
X-ray Generator			
Pulsed Fluoroscopy: Operating values	• kV range: variant B0: 40 - 110 kV variant B1+B2: 40 - 120 kV • mA range: variant B0: 0.2 - 16 mA variant B1: 0.2 - 16 mA variant B2: 0.2 – **20 mA**	• kV range: variant B0: 40 - 110 kV variant B1+B2: 40 - 120 kV • mA range: variant B0: 0.2 - 16 mA variant B1: 0.2 - 16 mA variant B2: 0.2 - 16 mA	Substantial equivalent. The characteristic line was changed to 20mA, which has no effect on the safety as it is below the maximum dose.
X-ray Tube			
Tube Type	stationary anode	stationary anode	Identical.
X-Ray Tubes	for variants B0, B1, and B2 • Avg. Power: 0.6 kW • Peak Power: 2,4kW • Max. Voltage: **125kV** for variants B0+B1 • Avg. Power:0.6 kW • Peak Power: 2.02 kW • Max. Voltage: 120 kV	for variants B0, B1, and B2 • Avg. Power: 0.6 kW • Peak Power: 2,4kW • Max. Voltage: 120kV for variants B0+B1 • Avg. Power:0.6 kW • Peak Power: 2.02 kW • Max. Voltage: 120 kV ○	Substantial equivalent The maximal voltage of the X-Ray tube for variants B0, B1, and B2 have the max. Voltage up to 125kV, but as the generator is up to 120kV the value was given as 120kV.
Monitors			
Display Monitor	The device can be equipped with monitors of different sizes • 19” Duo flat-screen monitor **(optionally with Quick Release)** • **27” flat screen monitor**	The device can be equipped with monitors of different sizes • 19” DUO flat-screen monitor • 24” flat screen monitor	Substantial equivalent. The 24” flat screen monitor has been discontinued by the manufacturer and have been replaced by 27” monitor.
Radiation Switches			
X-Ray foot switch	• Cable bound footswitch **(with or without protective bracket)** • optional: Wireless footswitch with an emergency cord the if battery is	• Cable bound footswitch • optional: Wireless footswitch with an emergency cord the if battery is low	Substantial equivalent All footswitches are available with

Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
	low **(with or without protective bracket)**		protective bracket.
Digital Imaging Processing			
Real-Time processing functions	• Recursive filter: 4 levels • Last Image Hold • Edge enhancement filter: 5 levels • Windowing and step windowing • Digital image rotation and reversal without radiation • Grayscale inversion • Digital collimators • Ziehm Adaptive Image Processing (ZAIP)	• Recursive filter: 4 levels • Stack filter 'Last Image Hold': 5 levels • Last Image Hold • Edge enhancement filter: 5 levels • Windowing and step windowing • Digital image rotation and reversal without radiation • Grayscale inversion • Digital collimators • Ziehm Adaptive Image Processing (ZAIP)	Substantial equivalent. Stack filter 'Last Image Hold' was discontinued.
Appli-cation-Oriented Anato-mical Programs (AOAP)	• Bone: Extremities, Trunk • Heart, Abdomen, Soft, Uro (option) • Vascular: Extremities, Trunk, Bolus	• Bone: Extremities, Trunk • Abdomen, Soft, Uro (option), Long Procedure Spine • Vascular: Extremities, Trunk, Bolus	Substantial equivalent. Long procedure spine was discontinued.

Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
Data Organization	• Patient-based data management with 16-image mosaic display • Pre-registration via DICOM Worklist (option) • Manual input or emergency registration • Calculated Dose Area Product (DAP) • DAP value tagged to stored image • Air Kerma dose display • Air kerma value tagged to the stored image • HIPAA security package (option) • Radiation Dose Structured Report (RDSR) • **Video Output** - **Full HD SDI (split display)** - **1920 x 1080p** - **60Hz** • Measured dose area product (DAP) with digital display (option)	• Patient-based data management with 16-image mosaic display • Pre-registration via DICOM Worklist (option) • Manual input or emergency registration • Calculated Dose Area Product (DAP) • DAP value tagged to stored image • Air Kerma dose display • Air kerma value tagged to the stored image • HIPAA security package (option) • Radiation Dose Structured Report (RDSR) • Measured dose area product (DAP) with digital display (option)	Substantial equivalent. As required by the IEC 60601-2-43 the modified device Ziehm Solo FD displays dose area product (DAP), air kerma rate and cumulative air kerma at the same time. An optimization have been made through the Video output, which have no influence on the device safety and effectiveness.
Device Options List			
Summary of above-described Options (details above)	• X-ray generator in different variants • Removable anti-scatter grid • Laser positioning device on the generator • Different locations and sizes of display monitor • Remote Solo Center • Footswitch with customer-specific switch assignment in variant cable bound or wireless • Cine loop with up to 30 frames per second • Measuring functions • Vascular package • Anatomical Marking Tool (AMT) • User administration (HIPAA) • Calculated or measured dose area product (DAP) and calculated Air Kerma • video printer • DICOM viewer software • Ziehm NetPort: DICOM 3.0 interface for digital network integration	• X-ray generator in different variants • Removable anti-scatter grid • Laser positioning device on the generator • Motor-driven angulation (A-Axis) • Variant "Portable" • Different locations and sizes of display monitor • Remote Solo Center • Footswitch with customer-specific switch assignment in variant cable bound or wireless • Cine loop with up to 30 frames per second • Measuring functions • Vascular package Anatomical Marking Tool (AMT) • User administration (HIPAA) • Calculated or measured dose area product (DAP) or calculated Air Kerma • video printer	Substantial equivalent Both options motor-driven angulation (A-axis) and Variant "Portable" were discontinued.

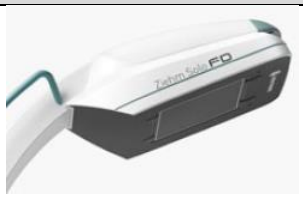
Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
	• WLAN interface for wireless data transfer • Viewing Station • **Field Transport Solution, incl. all-terrain wheels, towing and mounting device bar**	• DICOM viewer software • Ziehm NetPort: DICOM 3.0 interface for digital network integration • WLAN interface for wireless data transfer • Viewing Station	
Further Options	• video connector(s) for external flat-screen monitors (right and left monitor), optionally with analog or digital signal (DVI) • Key switch Power on/off • Interface for external separate radiation indication lamp	• video connector(s) for external flat-screen monitors (right and left monitor), optionally with analog or digital signal (DVI) • Key switch Power on/off or X-ray on/off • Interface for external separate radiation indication lamp	Substantial equivalent. Key switch Power on/off replaces X-ray on/off.

Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
Optional Accessories	• Sterile disposable covers • Skin protection	• Sterile disposable covers • Hand surgery table • Skin protection	Substantial equivalent. The optional Hand surgery table is no longer available. Note: Ziehm Imaging GmbH is not the manufacturer of the optional accessories
Software			
Level of Concern	Enhanced	Moderate	Identical; The term of level of concern has changed according to the Guidance "Content of Premarket Submissions for Device Software Functions", but there have been no additional changes to the device that have increased the level of concern.
Software	• **7.06.11** • Linux-based OS Ubuntu	• **7.00.3** • Linux-based OS Ubuntu	Updates and optimization of software features, which does not have influence on safety and effectiveness of the device.
Application / Indications for Use			

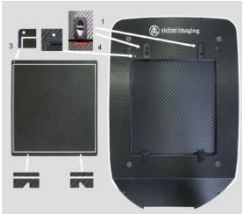
Model	Modified Ziehm Solo FD	Predicate *Ziehm Solo FD (K161976)*	Comparable Properties Substantial Equivalence Discussion
Indications for Use	The Ziehm Solo FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging. The 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. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. **The system is not intended for use near MRI systems.**	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.	Substantial equivalent The wording of the indications for use were updated. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Standards			
Standards	• ANSI/AAMIES60601-1:2005/**AMD1:2012** • IEC 60601-1-2: **2014** • IEC 60601-1-3: 2008/**AMD1:2013** • IEC 60601-1-6:2013/**AMD2:2020** • IEC60601-2-43: 2010/**AMD2:2019** • IEC60601-2-54:2009/**AMD2:2018** • IEC 60852-1:2007 • ISO 14971:2019	• IEC 60601-1:2005 • IEC 60601-1-2:2007 • IEC 60601-1-3:2008 • IEC 60601-1-6:2013 • IEC 60601-2-43:2010 • IEC 60601-2-54:2009 • IEC 60825-1:2007 • ISO 14971:2007	Applicable standards for the modified Ziehm Solo FD and the Solo FD predicate (K161976) remain as before. Newer versions of the standards have been applied.

For the comparison between a-Si and IGZO the Ziehm Vision FD (K193230) is used as reference device:

Model	Modified Ziehm Solo FD	Reference Device Ziehm Vision FD (K193230)	Comparable Properties Substantial Equivalence Discussion
510(k) Number	K231669	K193230	
Product Codes	OWB (interventional fluoroscopic x-ray system) Subsequent: JAA (system, x-ray, fluoroscopic, image-intensified), OXO (image-intensified fluoroscopic x-ray system, mobile)	OWB (interventional fluoroscopic x-ray system) Subsequent: JAA (system, x-ray, fluoroscopic, image-intensified), OXO (image-intensified fluoroscopic x-ray system, mobile)	Identical
Device Image/ General Overview			
Beam Limiter/ Collimator			
Collimator System	• Dedicated pre-collimator for flat panel detector • Collimator Rotation: +/- 90° • Iris and Asymmetric Slot Collimator • Virtual Collimation without radiation	• Dedicated pre-collimator for flat panel detector • Collimator Rotation: +/- 90° • Iris and Asymmetric Slot Collimator • Virtual Collimation without radiation	Identical collimator system. The maximum collimator opening is adjusted to the flat panel type.
Image Detector			
Image Detector	Flat Panel Detector	Flat Panel Detector	They are identical in the outer product design of the housing, both devices use safety shielding for radiation

Model	Modified Ziehm Solo FD	Reference Device Ziehm Vision FD (K193230)	Comparable Properties Substantial Equivalence Discussion
			suppression and use solid state x-ray image receptor (SSXI / FPD) The modified Ziehm Solo FD has additionally new 8 inch IGZO (Indium gallium zinc oxide) flat panel detector.
Detector Technology	• Type: CMOS Flat Panel Detector • Scintillator: Cesium-Iodide (CsI) • **Alternative Type: IGZO** • **Scintillator: Cesium-Iodide (CsI)**	• Type aSi (Amorphous Silicon) Flat Panel Detector • Scintillator: Cesium-Iodide (CsI) • Type CMOS Flat Panel Detector: • Scintillator: Cesium-Iodide (CsI)	IGZO based detectors are manufactured using processes that are similar to aSi detectors. The slight differences in used sensor glass technology does not have influence on safety and effectiveness of the C-arm product.
Detector Sizes	CMOS: Size: 21 cm x 21 cm (8”x 8”) Detector matrix: 2,053 x 2,051 pixels Magnifier 1: 1,536 x 1,536 pixels Magnifier 2: 1,024 x 1,024 pixels Dynamic Range: 1 x 1 binning: 84 dB 2 x 2 binning: 95 dB System resolution: 5,0 lp/mm **IGZO:** **Size: 21 cm x 21 cm (8”x 8”)** **Detector matrix: 1,536 x 1,536 pixels** **Magnifier 1: 1,024 x 1,024 pixels**	Variant 20.5cm x 20.5cm (8”x 8”) CMOS • Size: 20.5 cm x 20.5 cm • Detector matrix: 2,048 x 2,048 pixels • Magnifier 1: 1,536 x 1,536 pixels • Magnifier 2: 1,024 x 1,024 pixels • Dynamic Range: – 1 x 1 binning: 84 dB – 1 x 2 binning: 95 dB • System resolution (Nyquist): 5 lp/mm Variant 20cm x 20cm (8”x 8”) a-Si:	The active pixel area of the detector types are not identical but are very similar in image area of approx. 8 inch x 8 inch. The modified device Ziehm Solo FD with IGZO has a higher resolution size in comparison to reference device Ziehm Vision FD with a-Si FPD, which leads to

Model	Modified Ziehm Solo FD	Reference Device Ziehm Vision FD (K193230)	Comparable Properties Substantial Equivalence Discussion
	Magnifier 2: 768 x 768 pixels **Dynamic Range:** **1x1 binning: 84dB** **2x2 binning: 95dB** **System resolution: 3,7 lp/mm**	• Size: 19.9 cm x 19.9 cm • Detector matrix: 1,024 x 1,024 pixels • Magnifier 1: 768 x 768 pixels • Magnifier 2: 512 x 512 pixels • Dynamic Range: 94 dB • System resolution (Nyquist): 2.6 lp/mm Variant 30cm x 30cm (12'' x 12'') aSi: • Size: 29.8 cm x 29.8 cm • Detector matrix: 1,536 x 1,536 pixels • Magnifier 1: 1,024 x 1,024 pixels • Magnifier 2: 768 x 768 pixels • Dynamic Range: 94 dB • System resolution (Nyquist): 2.6 lp/mm Variant 30.7cm x 30.7cm (12'' x 12'') aSi: • Size: 31 cm x 31 cm • Detector matrix: 2,048 x 2,048 pixels • Magnifier 1: 1,536 x 1,536 pixels • Magnifier 2: 1,024 x 1,024 pixels • Dynamic Range: ≥86 dB • System resolution (Nyquist):3.3 lp/mm	better image quality. All other differences with regard to the used technology have no influence on safety and effectiveness of the C arm.
Anti-Scatter Grids			
Fixed anti-scatter grid	fixed anti-scatter grid: CMOS (8inch) • Pb 8/70 **IGZO (8inch)** • **Pb 8/70**	fixed anti-scatter grid: CMOS (8inch) • Pb 8/70 a-Si (8inch) • Pb 8/70 a-Si (12inch) • Pb 6/80	Identical values and material for both modified and reference device with 8 inch flat panel detectors.

Model	Modified Ziehm Solo FD	Reference Device Ziehm Vision FD (K193230)	Comparable Properties Substantial Equivalence Discussion
optional removable anti-scatter grid	 Removable Grid: CMOS (8inch) • Pb 8:1/70lines/cm **IGZO (8inch)** • **Pb 8:1/70 lines/cm**	 Removable Grid: CMOS (8inch) • Pb 8/70 a-Si (8inch) • Pb 8/70 a-Si (12inch) • Pb 6/80	Identical values and material for both modified and reference device with 8 inch flat panel detectors.

Conclusion of Table above: The changes of the proposed modified device Ziehm Solo FD described in the table do not change the fundamental control mechanism, operating principle or intended use found on predicate device and supports substantially equivalents to the predicate device Ziehm Solo FD (K161976) in accordance with its labeling.

Safety and Performance: The proposed Ziehm Solo FD C-arm's potential radiation, mechanical, and electrical hazards are identified and analyzed as part of risk management, and controlled by meeting the applicable CDRH 21CFR subchapter J performance requirements, recognized and general consensus standards**,** designing and manufacturing under Ziehm Imaging GmbH Quality System, and system verification and validation testing ensure the device performs to the product specifications and its intended use. The adherence to these applicable regulations and certification to Recognized Consensus Standards that apply to this product provides the assurance of device safety and effectiveness.

Summary of Non-Clinical Test Data: Ziehm Solo FD is based on direct modifications to cleared predicate device Ziehm Solo FD (K161976).

The design of the modified Ziehm Solo FD was completed in accordance with Ziehm Imaging GmbH Quality Management System Design Controls, 21 CFR 820 and applicable standards. Verification and Validation testing were successfully conducted on the device in compliance with FDA requirements as stated in the following documentation.

Testing regarding electrical safety according to ANSI/AAMI ES60601-1 and regarding electromagnetic compatibility according to IEC 60601-1-2 was performed. The test results show compliance with both standards.

Testing according to Guidance's "Radio Frequency Wireless Technology in Medical Devices" and "Design Considerations and Premarket Submissions Recommendations for Interoperable Medical Devices" show, neither the wireless features nor the interoperable interfaces of the device affect the safety and effectiveness.

Documentation provided demonstrates compliance of the modified device Ziehm Solo FD to 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 modified Ziehm Solo FD complies with 21 CFR 1020.30-32 Federal Performance Standards for X-Ray Fluoroscopic equipment and with relevant safety standards such as IEC 60601-1-3, IEC 60601-2-43, IEC 60601-2-54.

Non-clinical image comparison with sets of images with the modified device and the predicate shows equivalence regarding image quality.

With regard to the flat panel detector (SSXI), 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".
Furthermore, an assessment regarding the low dose functionality of the modified Ziehm Solo FD shows the ability to reduce dose for certain applications.

Software testing was performed as required by "Content of Premarket Submissions for Device Software Functions". Cybersecurity remains exactly the same as in the predicate device.

Determination of Substantial Equivalence:

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

Therefore, Ziehm Imaging GmbH believes the modified device Ziehm Solo FD C-arm image quality, safety and effectiveness supports a determination of substantial equivalence to the predicate device Ziehm Solo FD (K161976).

Compliance to FDA Guidance and Standards

FDA/CDRH From 3626 (5/11)	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.

General Standards / Regulations

MDSAP	Medical Device Single Audit Program (MDSAP)
Regulation (EU) 2017/745	Annex IX Chapter I, Section2 and 3 and Chapter III
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes Date: 2016

Recognized Consensuses Standards

ANSI/AAMI ES60601-1:	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, mod) Date: 2012 Conformance Standard #19-4
IEC 60601-1-2:	Medical Electrical Equipment, Part 1-2: General Requirements for Safety, Electromagnetic Compatibility Edition 4.0, Date: 2014-02 Conformance Standard #19-8
IEC 60601-1-3:	Medical Electrical Equipment, Part 1-3: Radiation Protection in Diagnostic X-ray Equipment Edition 2.1, Date: 2013-04 Conformance Standard #12-269
IEC 60601-1-6:	Medical Electrical Equipment, Part 1-6: Usability Edition 3.2, Date: 2020-07 Conformance Standard #5-132
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 2.2, Date: 2019-10 Conformance Standard #12-239
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 1.2, Date: 2018-06 Conformance Standard #12-317
IEC 61304:	Medical device software - Software life cycle processes Edition 1.1, Date 2015-06 Conformance Standard #13-79

IEC 60825-1: Safety of laser products, Equipment Safety, requirements, and user guide
Edition 2.0, Date: 2007-03
Conformance Standard #12-273

ISO 14971: Medical devices - Application of risk management to medical devices
Edition 3.0, Date: 2019-12
Conformance Standard #5-40

Determination of Substantial Equivalence:

Summary Bench Testing

Verification and Validation including hazard mitigations executed resulted in demonstrated system met Design Input and user needs.

The device was tested by the notified test laboratory resulting in device being certified compliant with ANSI/AAMI ES6060-1-1 series, including IEC 60601-2-54. Further device met all applicable sections of 21 CFR Subchapter J performance standards.

The modified Ziehm Solo FD development occurred under our design control processes, software development processes, and overall quality management system. They included but are not limited to,

- Risk Analysis
- Required reviews
- Design reviews
- Component testing
- Integration testing
- Performance testing
- Safety testing
- Product use testing

Performance bench testing included:

Non-clinical imaging and dose testing methods demonstrated the device capability to provide both reduced dose while maintaining image quality. Further in line with UCM089742- Premarket Assessment of Pediatric Medical Devices May 24, 2014 and UCM 302938- Pediatric Information for X-ray Imaging Device Premarket Notifications Nov 28, 2017. Non-clinical image and dose Lab testing, were employed. Anatomical phantoms were employed, image comparison sets taken were representative of both the adult and pediatric populations. A Radiologist performed an assessment of individual image sets. Radiologist conclusion, the image quality of the Ziehm Solo FD results in a comparable patient care to the reference device Ziehm Vision FD (K193230) and fulfils the requirements as stated by the intended use. Therefore, Ziehm Imaging GmbH believes the Ziehm Solo FD C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Ziehm Solo FD (K161976).

Conclusion: Ziehm Imaging GmbH considers the Ziehm Solo FD to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Solo FD (K161976) in accordance with its labeling.