Ziehm Imaging GmbH
% Steve Seeman
Director of Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.
6280 Hazeltine National Drive
ORLANDO, FL 32822

December 20, 2019

Re: K193230
Trade/Device Name: Ziehm Vision FD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: November 8, 2019
Received: November 25, 2019

Dear Mr. Seeman:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia Mills, Ph.D.
Division Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193230

Device Name
Ziehm Vision FD

Indications for Use *(Describe)*
The Ziehm Vision FD is intended for use in providing medical imaging for general populations. The device provides pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in Image geometry is required. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Volume 005 510 (k) Summary

November 08, 2019

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

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Device (Trade Name):	Ziehm Vision FD
510(k) Number:	unknown
Common /Usual Names:	Mobile Fluoroscopic C-Arm
Regulation number:	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	Interventional fluoroscopic x-ray system
Product Code:	OWB, JAA
Predicate Device:	Ziehm Vision FD (K061534)
Regulation number:	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	Interventional fluoroscopic x-ray system
Product Code:	OWB, JAA

General Description:

The Ziehm Vision 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. 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 monitor cart 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 Vision 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.

Intended Use

The Ziehm Vision FD is a mobile C-arm providing image data by means of a non-contact noninvasive x-ray technique during medical procedures and stores them

temporarily.

The system can be used for all medical indications where fluoroscopy is required.

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.

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	The system is intended for use with human bodies covering structures such as but not limited to the following, e.g. organs, tissue, bones, implants depending on the medical indication.
Indications for Use:	The Ziehm Vision FD is intended for use in providing medical imaging for general populations. The device provides pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in Image geometry is required. This device does not support direct radiographic film exposures and is not intended for use in performing mammography.
Technology:	The proposed modified device Ziehm Vision FD C-arm employs the same fundamental control, and scientific technology as that of our predicate device Ziehm Vision FD C-arm (K061534). The radiation control, X-Ray monoblock generator, power supplies as well as our advanced imaging system are very similar to the predicate device Ziehm Vision FD C-arm (K061534). Software architecture design is nearly identical to that of the predicate device Ziehm Vision FD C-arm (K061534). with modification of the software to support, lower dose functionality, processing applications related to the optional low dose range, image, Variable beam limiting device, and device specific features. The primary modifications of the C-Arm include a larger but virtually the same medical grade Image receptor, and a new CMOS image receptor as that of the predicate device Ziehm Vision FD C-arm (K061534). virtual beam limiting device for precise collimating to anatomical structures, new pre-filter for lower skin entrance dose imaging, incorporation of mechanical design improvements in the C-Arm and mobile workstation balancing, locks, and maneuverability improving operator workflow during extended procedures while keeping the essential profile of our predicate device Ziehm Vision FD C-arm (K061534).
Summary of Technological Characteristics:	The comparisons of the predicate device and the modified Ziehm Vision FD show, the scientific and technology characteristics of the Ziehm Vision FD are substantial equivalence to the predicate device Ziehm Vision FD (K061534)

Substantial Equivalence Table

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Model	Modified Ziehm Vision FD	Predicate Ziehm Vision FD (K061534)	Comparable Properties Substantial Equivalence Discussion
510(k) Number	Unknown at this time	K061534	TBD
Product Codes	OWB (interventional fluoroscopic x-ray system) Subsequent: JAA (system, x-ray, fluoroscopic, image-intensified)	OWB (interventional fluoroscopic x-ray system) Subsequent: JAA (system, x-ray, fluoroscopic, image-intensified)	Identical
Device Image/ General Overview	 **Ziehm Vision FD 8”x 8”**  **Ziehm Vision FD 12”x 12”**		The modified Ziehm Vision FD and the predicate Ziehm Vision FD (K061534) share the same general design. The predicate and new device variant share a substantial equivalence with regard to but not limited to the intended use, indications for use, operational functionality of imaging, use of the same mono block generator designs, X-ray tube types, thermal management control and radiation control, general system software, user interface controls, imaging acquisition, dimensional features, scientific technologies, risk assessment, risk analysis, safety and effectiveness. The variants between the predicate and the new device do not raise new safety or effectiveness concerns.
X-ray Generator			
Maximum Parameter	• <u>Variant A0:</u> max. 2.0 kW, max. 110 kV, max. 20 mA • **<u>Variant A1:</u>** **max. 2.4 kW,**	<u>Variant A0:</u> max. 2.0 kW, max. 110 kV, max. 20 mA	Predicate Ziehm Vision FD (K061534) and modified Ziehm Vision FD share the same generator variant A0.

	max. 120 kV, **max. 24 mA**		The new generator (variant A1) has a higher maximum power output, functions of 120 kV @ 24mA. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Pulsed Fluoroscopy: Operating values	• <u>Variant A0:</u> kV range: 40 - 110 kV mA range: 0.2 - 16 mA • **<u>Variant A1:</u>** kV range: 40 - **120 kV** mA range: 0.2 - 20 mA (8" FPD) mA range: 0.2 - **24 mA** (12" FPD)	<u>Variant A0:</u> kV range: 40 - 110 kV mA range: 0.2 - 20 mA	Predicate Ziehm Vision FD (K061534) and modified Ziehm Vision FD share the same generator variant A0. The new generator (variant A1) has a higher maximum power output.
Pulsed Fluoroscopy: Pulse and Duration	• pulse width: **7 - 23 ms** (12" FPD Fujifilm aSi) **10 - 40 ms** (12" FPD Varex, 8" FPD Varex aSi/CMOS) • pulse rate: 1, 2, 4, 8, 12.5, 25 pulse/s 1, 2, 5, 10, 15, 30 pulse/s	• pulse width: **10 - 30 ms** • pulse rate: 50 Hz: 1, 2, 4, 8, 12.5, 25 pulse/s 60 Hz: 1, 2, 5, 10, 15, 30 pulse/s	Although not identical the predicate Ziehm Vision FD (K061534) and modified Ziehm Vision FD both use the identical basic generator with Pulsed Fluoroscopy. They both incorporate features and operational parameters, such as but not limited to pulse fluoroscopy technology, pulse duration and pulse width control delivered power, X-ray tube anode loading, and heat dissipation. Pulse width is up to 40 ms as maximum and pulse rate of 25 p/s or 30 p/s are possible for modified Ziehm Vision FD, depending on the device configuration. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Digital Radiography (Snapshot) / Operating Values	• <u>Variant A0:</u> kV range: 40 - 110 kV mA range: up to 20 mA • **<u>Variant A1:</u>** kV range: 40 - **120 kV**	• kV range: 40-110 kV • mA range: up to 20 mA	Although the modified device is not identical to the predicate K061534. The general system exposure control

	mA range: up to **20 mA** (8” FPD Varex aSi) mA range: up to **24 mA** (8” FPD Varex CMOS, 12” FPD Varex aSi, 12” FPD Fujifilm aSi)		technology and operational functionality are identical in these regards for all available variants. Only the system programmable settings which define the limits of usable mA and kV are different. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Thermal Management	Active cooling	Active cooling	Identical
X-ray Tube			
Tube Type	stationary anode	stationary anode	Identical
Beam Limiter/ Collimator			
Collimator System	Devices with 8” x 8” Flat Panel Detector: • Dedicated pre-collimator for FPD • Collimator Rotation: +/- 90° • Iris Collimator: 50 – 198 mm diameter • Asymmetric Slot Collimator: 50 – 198 mm diameter • Virtual Collimation without radiation **Devices with 12” x 12” Flat Panel Detector:** • **Dedicated pre-collimator for FPD** • **Collimator Rotation: +/- 90°** • **Iris Collimator: 50 – 307 mm diameter** • **Asymmetric Slot Collimator: 50 – 307 mm diameter** • **Virtual Collimation without radiation**	Devices with 8” x 8” Flat Panel Detector: • Dedicated pre-collimator • Collimator Rotation: +/- 90° • Iris Collimator: 50 – 198 mm diameter • Asymmetric Slot Collimator: 50 – 198 mm diameter • Virtual Collimation without radiation Devices with 12” x 12” Flat Panel Detector: • **N/A**	The collimator system for the predicate and the modified Ziehm Vision FD with 8” x 8” Flat Panel Detector is identical. Since there is also a 12” x 12” Flat Panel Detector for the modified Ziehm Vision FD, a larger collimator is used. Even though the size is different the general design of both collimator systems is the same. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.

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Image Detector			
Image Detector	**Flat Panel Detector** 	**Flat Panel Detector** 	Although not identical in the cosmetic design of the housing, both devices use similar safety shielding for radiation suppression and use solid state x-ray image receptors (SSXI / FPD). These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Detector Technology	Variant aSi FPD: • Type: Amorphous Silicon Flat Panel Detector (aSi) • Scintillator: Cesium-Iodide (CsI) **Variant CMOS FPD:** • **Type: CMOS Flat Panel Detector** • Scintillator: Cesium-Iodide (CsI)	• Type: Amorphous Silicon Flat Panel Detector (aSi) • Scintillator: Cesium-Iodide (CsI)	Even though the detector materials of the Flat Panel Detector (FPD)/(SSXI) are not identical, both devices use solid state X-ray imagers (FPDs) having similar advantageous of higher image stability, higher DQE, image contrast range and higher geometric sharpness with regard to magnetic earth field effects which can distort an image as compared to an image intensifiers (II). These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Detector Sizes	Variant 20cm x 20cm (8”x 8”) aSi: • 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	• Size: 19.9 cm x 19.9 cm • Detector matrix: 1,024 x 1,024 pixels • Dynamic Range: 72 dB • System resolution: 2.6 lp/mm	The modified device and the predicate both use Solid State X-ray Imagers (FPD). The dimensions of the detectors are not identical but are very similar in image area for 8” x 8”. The modified Ziehm Vision FD introduces Flat Panel Detectors with 12” x 12”, which did not exist in the predicate. The detector matrices differ due to different pixel pitches. For the resulting

	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 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**	image on the monitor there is no significant difference because the image processing steps are equivalent. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Anti-Scatter Grids		

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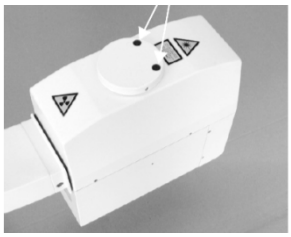
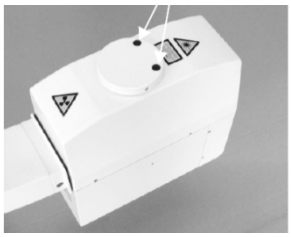
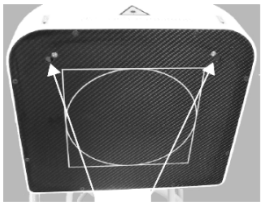
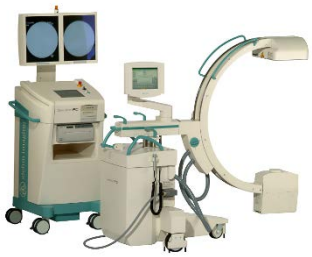
Fixed anti-scatter grid	fixed anti-scatter grid: **Pb 8/70**	fixed anti-scatter grid: **Pb 8/40**	The grids are equivalent for the predicate and modified Ziehm Vision FD.
optional removable anti-scatter grid	**Removable Grid: Pb 8/70** 	**Removable Grid: N/A, fixed anti-scatter grid only**	The predicate Ziehm Vision FD (K061534) is equipped with a fixed anti-scatter grid only, not a removable anti-scatter grid. However, the grid material and type of anti-scatter grid is comparable to the modified Ziehm Vision FD. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Laser Positioning Device			
Laser Positioning Device on Generator (optional)	Class 2M (IEC 60825-1), 635 nm 	Class 2M (IEC 60825-1), 635 nm 	Nearly Identical and equivalent laser positioning device
Laser Positioning Device on Image Detector (optional)	Class 2M (IEC 60825-1), 635 nm 	Class 2M (IEC 60825-1), 635 nm 	Although not identical in location they are nearly identical laser positioning and functionality for both predicate and modified device. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Electrical Requirements			
Electrical Requirements	• Power supply: 100-240 V_{AC} (± 10%), 50/60 Hz • Current consumption: 100-120 V: 10 A continuous, 22 A short-time 200-240 V: 8 A	• Power supply: 100-240 V_{AC} (± 10%), 50/60 Hz • Current consumption: 100-120 V: 10 A continuous, 22 A short-time 200-240 V: 8 A	Equivalent electrical specifications for predicate and modified Ziehm Vision FD.

	continuous, 16 A short-time • Max. impedance: **100-200 V: ≤ 0.3 Ω** **220-240 V: ≤ 0.6 Ω** • Class I equipment, Type B	continuous, 16 A short-time • Max. impedance: **≤ 0.6 Ω** • Class I equipment, Type B	
Mechanics			
Source-Image Receptor Distance (SID)	**109 cm**	**111 cm**	Source to Image Receptor Distance for the predicate and the modified device Ziehm Vision FD are not identical, but very similar. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Vertical Free Space	**87 cm**	**89.5 cm**	Vertical free space for the predicate and the modified device Ziehm Vision FD are not identical, but very similar. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
C-arm Depth	68 cm	68 cm	Identical
Width	80 cm	80 cm	Identical
Length of Mobile Stand	• **160 / 182 cm***(20/20 135° orbital) • optional: **180 / 202 cm***(20/20 165° orbital lowered C, 20/20 165° orbital with lifting column expansion) • optional: **176 / 198 cm*** (31/31 165° orbital) * depending on configuration	**160 / 182 cm**	The length of the predicate and the modified device is similar but not identical. The dimensions vary for the modified Ziehm Vision FD depending on the configuration of image receptor size. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Height of Mobile Stand	• **155 / 200 cm***(20/20 135° orbital) • optional: **155 / 197 cm***(20/20 165° orbital lowered C, 31/31 165° orbital) • optional: **158 / 220 cm*** (20/20 165°	**158 / 201 cm**	Although not identical the difference between the predicate and modified device is a result of different configurations of the device. The dimensions vary for the modified Ziehm Vision FD

	orbital with lifting column expansion) * depending on configuration		depending on the configuration of image receptor size. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Manually Operated A-Axis (angulation)	+/- 225° (450°)	+/- 225° (450°)	Identical
Manually Operated B-Axis (swiveling)	+/- 10° (20°)	+/- 10° (20°)	Identical
Manually Operated C-Axis (orbital)	**-120° / +45° (165°)**	**-90° / +45° (135°)**	Although the modified Ziehm Vision FD is not identical the additional 30° of rotational movement in the C-Axis as compared to the predicate provides an improved user range of motion when performing oblique imaging and in no way diminishes or changes the devices effectiveness, therefore, the operation of the C-Axis is substantially equivalent to the predicates. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Manually Operated Y-Axis (horizontal)	22 cm	22 cm	Identical
Motor Driven Z-Axis (vertical)	**42 cm** optional: **63 cm**	**43 cm**	Although not identical, the basic configuration of predicate and modified device is equivalent. The modified device also provides an optional extended lift column which results in different dimensions. The

			dimensions vary for the modified Ziehm Vision FD depending on the configuration of image receptor size. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Weight	Mobile Stand: max. **337 kg** Monitor Cart: max. **233 kg**	Mobile Stand: max. 245 kg Monitor Cart: max. 160 kg	Although not identical, modified Ziehm Vision FD incorporates additional features (e.g. Remote Vision Center, articulating monitor arm) which result in a slightly higher weight. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Monitors			
Display Monitor	The device can be equipped with monitors of different sizes • **dual 19” flat screen monitors** • **26” color flat screen monitor** • **27” flat screen monitor** • **32” flat screen monitor**	The device can be equipped with monitors of different sizes • dual 18” flat screen monitors • dual 20” flat screen monitors	The modified Ziehm Vision FD can be equipped with up-to-date monitors in different sizes. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Location of Display Monitor	Monitor on Monitor Cart  **optional video port connections used to extend video to additional monitor**	Monitor on Monitor Cart 	The monitors of both devices are located at the Monitor Cart. The modified Ziehm Vision FD can also be ordered with external video port connections to extend video to an additional external monitor. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.

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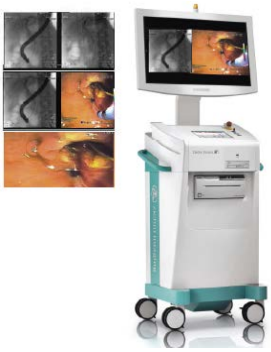
mounted on external support arm

	Monitor Cart with fix or **articulating monitor arm** (option)	Monitor Cart with fix monitor arm	
Monitor Arm	 		The modified device also provides an optional articulating monitor arm mounted on the monitor cart. This allows the user to move the monitor in several directions to provide the most ergonomic viewing angle for the clinician in diverse OR set-ups. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
	26” color flat screen monitor	dual **18”** flat screen monitors	
Endoscopy Display Option			Identical operation. A 26’’ monitor replaces the dual 18” monitors. This allows the Monitor Cart to display color images that are routed by a video switch directly from an external endoscopic video source. The C-ram only displays the video out from external endoscopic device for visualization of endoscopic procedures. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.

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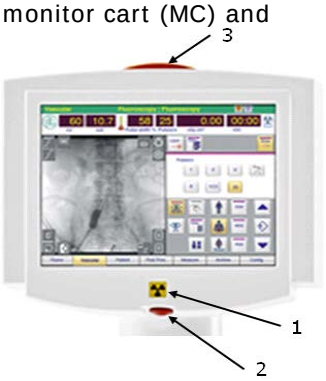
User Interface			
Control Elements Touch Panel	Vision Center (User touch panel and X-ray Control) on mobile stand (MS) and monitor cart (MC) and  **Remote Vision Center** **1 Radiation Button** **2 Emergency Stop Button** **3 X-Ray indication lamp**	Vision Center (User touch panel and X-ray Control) on mobile stand (MS) and monitor cart (MC) 	Although the Vision Center on the predicate Ziehm Vision FD (K061534) is not identical in design of the housing and implementation of the radiation button, emergency stop, and radiation indicator, the user interface for exposure control, work flow of procedures and selection of features and functions is essentially identical as can be seen in the pictures to the left. The modified Ziehm Vision FD can optionally be equipped with a Remote Vision Center. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Radiation Switches			
X-Ray hand switch	• cable bound hand switch on Mobile Stand	• cable bound hand switch on Mobile Stand	Identical
X-Ray foot switch	• Cable bound footswitch • **optional: Wireless footswitch with emergency cord if battery is low** • **optional: protective bracket for footswitch**	• Cable bound footswitch	Although not identical, the modified device provides up-to-date variants for the footswitch. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Further X-ray switches	**Radiation button at “Vision Center”** **Radiation button at “Remote Vision Center”**	N/A	Although the Vision Center on the predicate Ziehm Vision FD (K061534) is not identical in design of the housing and implementation of the radiation button, emergency stop, and radiation indicator; the Vision Center used on the predicate still has the radiation indicator as a

			lighted radiation symbol on the touch panel display (GUI). These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Digital Image Processing			
Real-Time processing functions	• Recursive filter: 4 levels • Stack filter ('Last Image Hold'): 5 levels • Edge enhancement filter: 5 levels • Windowing and step windowing • Digital image rotation and reversal without radiation • Grayscale inversion • Virtual collimators • **Ziehm Adaptive Image Processing (ZAIP)**	• Recursive filter: 4 levels • Stack filter ('Last Image Hold'): 5 levels • Edge enhancement filter: 5 levels • Windowing and step windowing • Digital image rotation and reversal without radiation • Grayscale inversion • Virtual collimators	Modified Ziehm Vision FD contains "Ziehm Adaptive Image Processing" (ZAIP). ZAIP enhances the image quality of Ziehm C-arms with flat-panel detector. ZAIP uses hardware-based filters and the latest algorithms for noise filtering, edge enhancement and dose optimization to achieve the best results in intraoperative imaging. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Application-Oriented Anatomical Programs (AOAP)	• Bone: Extremities/ cervical spine/ head, Trunk • Heart, Abdomen, Soft • Vascular (option): Extremities, Trunk, Bolus • Urology (option) • Endo (option)	• Bone • Heart, Abdomen, Endo, Uro • Soft	Although not identical the predicate and the modified device have similar anatomical programs which the user can select, except for the vascular AOAP. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Additional Functions	• Metal • **Reposition** • High Quality • **Low Dose** • Obese Patient • Motion	• Metal • High Quality • Large Patient • Motion	The predicate shares nearly identical functions with exception for the modified device provides a Low Dose setting and Reposition function. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.

Image Acquisition	• Auto save • Cine loop with auto-playback (option) – sequential image storage and display: **1-8** or **1-12.5** or **1-25 frames per second** **– start, stop and replay rate controls**	• Auto save • Cine loop with auto-playback (option) – sequential image storage and display: 50 Hz: 1-8 or 1-12.5 or 1-25 frames/s 60 Hz: **1-10** or **1-15** or **1-30 frames per second** - start, stop and replay rate controls	Nearly identical operation and control, the only exception is the frame rates. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Post-Processing Functions	• Edge enhancement: 5 levels • Zoom: **3 levels** • Image rotation • Windowing and step windowing • Grayscale inversion • Image cropping (digital collimators) • Digital measurement functions: distance/angle (option)	• Edge enhancement: 5 levels • Zoom: **7 levels** • Image rotation • Windowing and step windowing • Grayscale inversion • Image cropping (digital collimators) • Digital measurement functions: distance/angle (option)	The modified device shares nearly identical post-processing functions with the predicate except for zoom levels. The Zoom levels do not raise new safety or effectiveness concerns with regard to the predicate device.
DSA Functions (option)	• DSA real-time subtraction with re-masking capability • MSA max. opacification sequence • **Single frame, Multiframe RSA (road-mapping)** • Pixel shift / landmarking	• DSA real-time subtraction with re-masking capability • MSA max. opacification sequence • **RSA road-mapping** • Pixel shift / landmarking	The basic DSA functionality of the modified device is identical to the predicate. However, the modified device has some additional functions. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
CO_2 Package (option)	Automatic image optimization when using negative contrast medium in vascular modes	Automatic image optimization when using negative contrast medium in subtraction modes	Identical
Anatomical Marking Tool - AMT (Option)	• **Mark anatomical structures** • **Indicate side of body**	N/A	The predicate does not provide an anatomical marking tool. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Digital Memory	• Storage capacity: up to **100,000** images	• Storage capacity: up to 55,000 images	Even though not identical, modified Ziehm Vision FD and the predicate Ziehm

	• Memory matrix: 1,024 x 1,024 pixels	• Memory matrix: 1,024 x 1,024 pixels	Vision FD (K061534) are very similar in digital memory. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Data Organization	• Patient-based data management with 16-image mosaic display • Pre-registration via DICOM Worklist (option) • Manual input or emergency registration • HIPAA security package • **Radiation Dose Structured Report (RDSR)**	• Patient-based data management with 16-image mosaic display • Pre-registration via DICOM Worklist (option) • Manual input or emergency registration • HIPAA security package	The predicate and modified Ziehm Vision FD have the same data Organization. However, the modified device provides additional functionality required by new standards for dose reporting. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
HIPAA	Option for HIPAA Security	Option for HIPAA Security	Identical
Dose Area Product meter	• calculated Air Kerma • optional: calculated Dose Area Product (DAP) • optional: measured Dose Area Product (DAP) • DAP/air kerma value tagged to stored image	• calculated Air Kerma • optional: calculated Dose Area Product (DAP) • optional: measured Dose Area Product (DAP) • DAP/air kerma value tagged to stored image	Identical
Archiving External Media (optional)	• Video printer (option) • USB port: – storage capacity depends on storage medium – formats: DICOM, TIFF, Multimedia (AVI) – downsized formats: DICOM, JPG • DVD-RW drive (option): – 4.7 GB storage capacity – formats: DICOM, TIFF, Multimedia (AVI) – downsized formats: DICOM, JPG	• Video printer • USB port: – storage capacity depends on storage medium – formats: DICOM, TIFF, Multimedia (AVI) – downsized formats: DICOM, JPG • **3.5” floppy disk drive:** – **storage capacity: 1 image** • DVD-RW drive: – 4.7 GB storage capacity – formats: DICOM, TIFF, Multimedia (AVI)	The predicate was also equipped with an optional 3.5” floppy disk. However, the 3.5” floppy is no longer the standard for external image storage in medical facilities. Facilities now require USB options. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.

		– downsized formats: DICOM, JPG	
Archiving / Networking (optional)	• Ziehm NetPort: DICOM 3.0 interface (RJ45 or **WLAN** connection) for digital network integration • 'Primary Capture 'mode • WLAN interface for wireless data transfer	• Ziehm NetPort: DICOM 3.0 interface (RJ45 or **F0** connection) for digital network integration • 'Primary Capture 'mode • WLAN interface for wireless data transfer	The basic archiving / networking functionality of the modified device is identical to the predicate. However, the modified device provides up-to-date functionality. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Available DICOM Classes	• multiframe capability and Storage Commitment • Print Class • Media Class • Worklist Class incl. Modality Performed Procedure Step (MPPS) • Query Class • Retrieve Class • Verification Class	• multiframe capability and Storage Commitment • Print Class • Media Class • Worklist Class incl. Modality Performed Procedure Step (MPPS) • Query Class • Retrieve Class • Verification Class	Identical
Application / Indications for Use			
Indications for Use	The Ziehm Vision FD is intended for use in providing medical imaging for **general populations**. The device provides pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in Image geometry is required. **This device does not support direct radiographic film exposures and is**	The Ziehm Vision FD is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiae, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in image geometry is required. **At the discretion of a physician the device may be used for other imaging applications.**	The Indications for Use for the modified Ziehm Vision FD are almost identical to the predicate, representing identical indications for use and type of interventional and fluoroscopic procedures. However, the IFU for the modified device Ziehm Vision FD excludes the following items from the predicate. • "**At the discretion of a physician the device may be used for other imaging applications".** • "**device does not support direct radiographic film exposures and is not**

	not intended for use in performing mammography.		**intended for use in performing mammography”.** Further the new device indication for use includes the statement that the modified device is intended for **“general populations”** in response to FDA Guidance UCM 356190-Pediatric Information for X-Ray imaging device per-market notifications. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
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 lies with the attending physician or attending surgeon.	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 lies with the attending physician or attending surgeon.	Identical
Application Environment	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 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%.	Proper and safe operation of the system requires adequate transportation, storage, assembly and installation as well as appropriate use and maintenance. The limiting values indicated in this user manual must not be exceeded; this applies also when putting the system into service.	Even though the application environment for the predicate was not defined in such detail as for the modified device, the general application environment is equivalent. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.

Human Factors	Device labeling defines that only trained and instructed qualified personnel are allowed to operate the system.	Device labeling defines that only trained and instructed qualified personnel are allowed to operate the system.	Identical
Material / Compatibility			
Materials / Biocompatibility	N/A. The device is a non-contact medical device that performs Fluoroscopic imaging and therefore, is not required to be in contact with patient to perform its intended use as a mobile x-ray System.	N/A. The device is a non-contact medical device that performs Fluoroscopic imaging and therefore, is not required to be in contact with patient to perform its intended use as a mobile x-ray System.	Identical
Inter-operability (options)	• Ziehm NaviPort 2D • Ziehm NetPort (DICOM 3.0 interface) • Generic interface to injector • **Z-Conference (video server)** • Video transmission (video connector or **wireless video**) • Interface for external separate X-ray indication lamp	• Ziehm NaviPort 2D • Ziehm NetPort DICOM 3 Networking • Generic interface to injector • Video transmission (video connector) • Interface for external separate X-ray indication lamp	Although not identical to the predicate, modified Ziehm Vision FD provides more up-to-date network options. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
Sterility			
Sterility	N/A. The device is not a sterile product.	N/A. The device is not a sterile product.	Identical

Conclusion of Table above: The changes and similarities of the proposed Ziehm Vision FD C-arm described in the table do not change the control mechanism, operating principle, energy type, or intended use found on predicate device and supports substantially equivalents to the predicate device Ziehm Vision FD (K061534) in accordance with its labeling.

Adverse Effects on Health: The proposed Ziehm Vision 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.

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Summary of Non-Clinical Test Data:

Ziehm Vision FD is based on direct modifications to cleared predicate device Ziehm Vision FD (K061534).

The design of the modified Ziehm Vision 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 Vision 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 Vision 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), test documentation provided in this submission demonstrates compliance of the modified device Ziehm Vision 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 Vision FD shows the ability to reduce dose for certain applications.

Software testing was performed as required by "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

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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 Vision FD C-arm image quality, safety and effectiveness supports a determination of substantial equivalence to the predicate device Ziehm Vision FD (K061534).

Compliance Standards:

Compliance to FDA Guidance and Standards

FDA/CDRH From 3626 (8/17)	"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)
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 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 3.1, Date: 2013-10 Conformance Standard #5-89
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 Conformance Standard #12-202

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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 1.1, Date: 2015 Conformance Standard #12-296
IEC 60825-1:	Safety of laser products, Equipment Safety, requirements, and user guide Edition 2.0, Date: 2007 Conformance Standard #12-273
ISO 14971:	Medical devices - Application of risk management to medical devices Edition 2.0, Date: 2007 Conformance Standard #5-40

Summary of Clinical Test Data:

The modified Ziehm Vision FD mobile fluoroscopic C-arm system did not require live human clinical studies to support substantial equivalence in accordance with the FDA guidance Documents, 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.

Therefore, Ziehm Imaging GmbH conducted an image comparison study employing the use of anthropomorphic phantoms in establishing substantial equivalence based on the modifications to the proposed device and the bench data taken. Evaluation of the individual images arranged in image sets was conducted by a board-certified Radiologist. His conclusion was the image quality combined with a reduced patient dosage will result in a comparable patient care to the Predicate device Ziehm Vision FD (K061534).).
His comparison of the dose and images provided further evidence in addition to the laboratory performance data that the complete system works as intended and is substantially equivalent to the predicate device

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 Vision 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. Anthropomorphic (PMMA material) phantoms and anatomical simulation 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 Vision FD results in a comparable patient care to the Predicate device Ziehm Vision FD (K061534). and fulfils the requirements as stated by the intended use. Therefore, Ziehm Imaging GmbH believes the Ziehm Vision FD C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Ziehm Vision FD (K061534).

Conclusion: Ziehm Imaging GmbH considers the modified Ziehm Vision FD to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Vision FD (K061534) in accordance with its labeling.

End of 510(k) Summary