November 20, 2023

Ziehm Imaging GmbH
% Stefan Fiedler
Director Quality Management & Regulatory Affairs
Lina-Ammon-Strasse 10
Nuremberg, Bavaria 90471
GERMANY

Re: K231692
Trade/Device Name: Ziehm Vision RFD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA, OWB, OXO
Dated: October 23, 2023
Received: October 23, 2023

Dear Stefan Fiedler:

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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K231692

Device Name

Ziehm Vision RFD

Indications for Use *(Describe)*

The Ziehm Vision RFD is intended for use in providing medical imaging for adult and pediatric populations, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

K231692

November 20, 2023

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

Submitter Address:	Ziehm Imaging GmbH Lina-Ammon-Strasse 10 90471 Nuremberg Germany Phone: +49 911 66067 0 Fax: +49 911 66067 390
Primary Contact Person Agent:	Kevin Bridgman VP Quality Assurance & Regulatory Affairs Ziehm-Orthoscan, Inc. 14555 N 82nd St Scottsdale AZ, 85260
Secondary Contact Person:	Stefan Fiedler Director QM/RA Ziehm Imaging GmbH Phone: +49 911 66067 219 Fax: +49 172 8651712
Device (Trade Name):	Ziehm Vision RFD
Common /Usual Names:	Mobile Fluoroscopic C-Arm
Regulation:	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Product Code:	JAA; OWB; OXO
Classification:	II

Predicate Device:	K203428 - Ziehm Vision RFD
Decision Date:	03/17/2021
Regulation:	21CFR 892.1650
Regulation Description Name:	Image-intensified fluoroscopic x-ray system
Product Code:	JAA; OWB; OXO

Summary of Technological Characteristics

The Ziehm Vision RFD employs X-rays as its imaging technology for visualizing human anatomy. The X-ray tube in the generator produces X-rays, guided toward the patient under control of the user at the direction of a physician who determines the specific clinical procedure. The images from the system assist the physicians in visualizing the patient's anatomy. This visualization helps to localize regions of pathology and for surgical procedures. The device provides both real-time image capture and post capture visualization and of in vivo surgical procedures and post-surgical outcomes.

The Ziehm Vision RFD mobile fluoroscopy system is a flat panel detector (FPD) and fluoroscopic X-ray imaging system consisting of two mobile units: a Mobile Stand (C-Arm) and a Monitor Cart/Workstation. The Mobile Stand is comprised of a mono-block high voltage generator, X-ray control, and a C-Profile which is "C" shaped and supports the X-ray generator, and the image receptor Flat Panel Detector (FPD).

The mobile stand supports the optional wireless footswitch for optimum positioning for the surgeon by removing the cable on the floor.

The Monitor Cart is a mobile platform that connects to the Mobile Stand by a cable, and which integrates the LCD flat panel display monitors, image processing, user controls and image recording devices. Interfaces provided for optional peripheral devices such as external monitors, thermal video printers, wireless video display, wireless video server, injector connection and image storage devices (USB, DVD) and DICOM fixed wired and wireless network interfaces.

The proposed modified device Ziehm Vision RFD C-arm employs the same fundamental control, and substantially equivalent scientific technology as that of our predicate device Ziehm Vision RFD C-arm (K203428).

The radiation control, X-Ray monoblock generator, power supplies as well as our advanced imaging system are the same as the predicate device Ziehm Vision RFD C-arm (K203428).

Software architecture design is substantially equivalent to that of the predicate device Ziehm Vision RFD C-arm (K203428).

The primary modification of the C-Arm includes a 12 inch IGZO (Indium gallium zinc oxide) flat panel detector (FPD) which have substantially equivalent technology characteristics as our predicate device Ziehm Vision RFD C-arm (K203428). The new 12 inch IGZO FPD is an addition to already introduced a-Si and CMOS FPD's. 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) 8inch and 12 inch aSi, 8 inch and 12 inch CMOS and the only difference to the predicate Ziehm Vision RFD is the new 12 inch IGZO panel.

The comparison of the predicate device and the modified devices shows that the scientific and technical characteristics of the Ziehm Vision RFD are substantially equivalent as those of the Ziehm Vision RFD predicate device (K203428).

Intended Use

The Ziehm Vision RFD 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 Vision RFD is intended for use in all medical indications requiring fluoroscopy. The Ziehm Vision RFD is intended for use to provide image data specifically but not limited in the field of interventional radiology and cardiology as well as in cardiac surgery and in hybrid applications. 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. These devices are not intended for use in performing mammographic exposures. The systems are not intended for use near MRI systems.

Indications for Use:

The Ziehm Vision RFD is intended for use in providing medical imaging for adult and pediatric populations, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine, and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required. 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 in all MRI environments.

Device Comparison Table

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

Model	**Modified** **Ziehm Vision RFD**	**Predicate** **Ziehm Vision RFD (K203428)**	**Comparable Properties Substantial Equivalence Discussion**
510(k) Number	K231692	K203428	-
Classification	Class II	Class II	Identical
Product Code	JAA (system, x-ray, fluoroscopic, image-intensified)	JAA (system, x-ray, fluoroscopic, image-intensified)	Identical
Application / Indications for Use			
Indications for Use	The Ziehm Vision RFD is intended for use in providing medical imaging for adult and pediatric populations, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional	The Ziehm Vision RFD is intended for use in providing medical imaging for adult and pediatric populations, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic,	Identical

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K203428)	Comparable Properties Substantial Equivalence Discussion
	angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine, and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required. 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 in all MRI environments.	urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine, and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required. 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.	

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K203428)	Comparable Properties Substantial Equivalence Discussion
Digital Radiography (Snapshot) / Operating Values	• Variant 20kW kV range: 40 - 120 kV mA range: up to 200 mA • Variant 25kW kV range: 40 - 120 kV mA range: up to 250 mA Variant 30 kW kV range: 40 - 120 kV mA range: up to 300 mA	• Variant 20kW kV range: 40 - 120 kV mA range: up to 200 mA • Variant 25kW kV range: 40 - 120 kV mA range: up to 250 mA Variant 30 kW kV range: 40 - 120 kV mA range: up to 300 mA	Identical
Beam Limiter/ Collimator			
Collimator System	Asymmetrical Collimator: • Devices with 12inch and 8inch cm Flat Panel Detectors: • Dedicated pre-collimator for FPD • Collimator Rotation: +/- 90° • Iris and Asymmetric SlotCollimator: - 50 – 307 mm diameter (12 inch FPD CMOS **& IGZO**) -50 – 298 mm diameter (12 inch FPD aSi) - 50-205 mm diameter (8inch FPD CMOS) • Virtual Collimation without radiation	Asymmetrical Collimator: • Devices with 12inch and 8inch cm Flat Panel Detectors: • Dedicated pre-collimator for FPD • Collimator Rotation: +/- 90° • Iris and Asymmetric SlotCollimator: - 50 – 307 mm diameter (12 inch FPD CMOS) -50 – 289 mm diameter (12 inch FPD aSi) - 50-205 mm diameter (8inch FPD CMOS) - 50-198 mm diameter (8inch FPD aSi) • Virtual Collimation without radiation	The collimator system of the IGZO is the same as the already introduced CMOS FPD.
Image Detector			
Detector Technology	Variant aSi FPD: • Type: Amorphous Silicon Flat Panel Detector (aSi) • Scintillator: Cesium-Iodide (CsI) Variant CMOS FPD:	Variant aSi FPD: • Type: Amorphous Silicon Flat Panel Detector (aSi) • Scintillator: Cesium-Iodide (CsI) Variant CMOS FPD: • Type: CMOS Flat Panel Detector	The new 12 inch IGZO (FPD) is an additional flat panel type beside the already established FPDs based on aSi (amorphous Silicon) and CMOS (Complementary Metal Semi-conductor)

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K203428)	Comparable Properties Substantial Equivalence Discussion
	• Type: CMOS Flat Panel Detector • Scintillator: Cesium-Iodide (CsI) **<u>Variant IGZO FPD:</u>** • **Type: IGZO Flat Panel Detector** • **Scintillator: Cesium-Iodide (CsI)**	• Scintillator: Cesium_	technology. IGZO FPDs are using the aSi/IGZO sensor technology
Detector Sizes	<u>30cm x 30cm (12inch) aSi (amorphous silicon TFT technology)</u> • 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 • Scintillator cesium iodide • Dynamic Range: 94 dB • DQE: 77% • MTF>50%@1lp/mm • Pixel size 194µm • Garyscale 65,536 gray scale values (16bit) • System resolution (Nyquist): 2.6 lp/mm <u>Variant 31 cm x 31 cm (12inch) CMOS Technology:</u> • Size: 30.7 cm x 30.7 cm • Detector matrix: 3,072 x 3,072 pixels • Magnifier 1: 2,048x 2,048 pixels • Magnifier 2: 1,536 x 1,536 pixels • Dynamic Range: - 1x1 binning:84 dB - 2x2 binning: 95 dB	<u>30cm x 30cm (12inch) aSi (amorphous silicon TFT technology)</u> • 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 • Scintillator cesium iodide • Dynamic Range: 94 dB • DQE: 77% • MTF>50%@1lp/mm • Pixel size 194µm • Garyscale 65,536 gray scale values (16bit) • System resolution (Nyquist): 2.6 lp/mm <u>Variant 31 cm x 31 cm (12inch) CMOS Technology:</u> • Size: 30.7 cm x 30.7 cm • Detector matrix: 3,072 x 3,072 pixels • Magnifier 1: 2,048x 2,048 pixels • Magnifier 2: 1,536 x 1,536 pixels • Dynamic Range: - 1x1 binning:84 dB - 2x2 binning: 95 dB	The active pixel area of the detector types are not identical but are very similar in image area of approx. 12 inch x 12 inch. IGZO detector has higher number of pixel and smaller pixel pitch accordingly; therefor the IGZO detector has better resolution compared to aSi detectors. This shows the technical advantage over the established aSi systems. The slight differences in detector and pixel size does not have influence on safety and effectiveness of the C-arm.

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K203428)	Comparable Properties Substantial Equivalence Discussion
	• Scintillator: cesium iodide • DQE: 75% • MTF: - 1 lp/mm: 55 % - 2 lp/mm: 23 % - 3 lp/mm: 10 % - 4 lp/mm: 5 % • Pixel size 100 µm • Garyscale 65,536 gray scale values (16bit) System resolution (Nyquist): 5 lp/mm <u>20 cm x 20 cm (8inch) aSi (amorphous silicon TFT technology)</u> • 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 • Scintillator cesium iodide • Dynamic Range: 94 dB • DQE: 77% • MTF>50%@1lp/mm • Pixel size 194µm • Garyscale 65,536 gray scale values (16bit) • System resolution (Nyquist): 2.6 lp/mm <u>Variant 21 cm x 21 cm (8inch) CMOS Technology:</u> • Size: 20.5 cm x 20.5 cm • Detector matrix: 2,053x 2,053 pixels • Magnifier 1: 1,536 x 1,536 pixels	• Scintillator: cesium iodide • DQE: 75% • MTF: - 1 lp/mm: 55 % - 2 lp/mm: 23 % - 3 lp/mm: 10 % - 4 lp/mm: 5 % • Pixel size 100 µm • Garyscale 65,536 gray scale values (16bit) System resolution (Nyquist): 5 lp/mm <u>20 cm x 20 cm (8inch) aSi (amorphous silicon TFT technology)</u> • 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 • Scintillator cesium iodide • Dynamic Range: 94 dB • DQE: 77% • MTF>50%@1lp/mm • Pixel size 194µm • Garyscale 65,536 gray scale values (16bit) • System resolution (Nyquist): 2.6 lp/mm <u>Variant 20.5 cm x 20.5 cm (8inch) CMOS Technology:</u> • Size: 20.5 cm x 20.5 cm • Detector matrix: 2,048x 2,048 pixels • Magnifier 1: 1,536 x 1,536 pixels • Magnifier 2: 1,024 x 1,024 pixels	

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K203428)	Comparable Properties Substantial Equivalence Discussion
	• Magnifier 2: 1,024 x 1,024 pixels • Dynamic Range: - 1x1 binning:84 dB - 2x2 binning: 95 dB • Scintillator: cesium iodide • DQE: 75% • MTF: - 1 lp/mm: 55 % - 2 lp/mm: 23 % - 3 lp/mm: 10 % - 4 lp/mm: 5 % • Pixel size 100 µm • Garyscale 65,536 gray scale values (16bit) System resolution (Nyquist): 5 lp/mm **<u>31 cm x 31 cm (12inch) IGZO (IGZO technology)</u>** • **Size: 30.7 cm x 30.7 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** • **Scintillator cesium iodide** • **DQE:** - **80% @ 0 lp/mm** - **67% @ 0.5 lp/mm** - **59% @ 1 lp/mm** - **46% @ 2 lp/mm** • **MTF** - **0.5 lp/mm: 82%** - **1 lp/mm: 60%** - **2 lp/mm: 30%** • **Pixel size 150µm** • **Garyscale 65,536 gray scale values (16bit)**	• Dynamic Range: - 1x1 binning:84 dB - 2x2 binning: 95 dB • Scintillator: cesium iodide • DQE: 75% • MTF: - 1 lp/mm: 55 % - 2 lp/mm: 23 % - 3 lp/mm: 10 % - 4 lp/mm: 5 % • Pixel size 100 µm • Garyscale 65,536 gray scale values (16bit) System resolution (Nyquist): 5 lp/mm	

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K203428)	Comparable Properties Substantial Equivalence Discussion
	• **System resolution (Nyquist): 3.3 lp/mm**		
Anti-Scatter Grid			
Anti-scatter grid	fixed anti-scatter grid: a-Si (8inch & 12inch) • Pb 8/70 CMOS (8inch & 12inch) • Pb 8/70 **IGZO (12inch)** **Pb 6/80**	fixed anti-scatter grid: a-Si (8inch & 12inch) • Pb 8/70 CMOS (8inch & 12inch) • Pb 8/70	The grids for the a-Si and CMOS FPD are identical for the predicate Ziehm Vision RFD (K203428) and modified Ziehm Vision RFD. The grid of the new IGZO has slightly different values compared to the anti-scatter grids for the other two FPD's.
Digital Image Processing			
Application-Oriented Anatomical Programs (AOAP)	• Bone: Extremities, Trunk • Heart, Abdomen, Soft • **Cardio (option): Heart Coro , Heart EP** • Vascular (option): Extremities, Trunk, Bolus, DSA, MSA, RSA • Urology (option) • Endo (option) •	• Bone: Extremities, Trunk • Heart, Abdomen, Soft • Vascular (option): Extremities, Trunk, Bolus, DSA, MSA, RSA • Urology (option) • Endo (option)	Cardio application was reorder of anatomical program and an optimization of already existing heart APR.
Anatomical Marking Tool - AMT (Option)	• Mark anatomical structures • Indicate side of body • 2D measurement function Enhanced Vessel Visualization(EVV)	• Mark anatomical structures • Indicate side of body • 2D measurement function	Identical, EVV was already part of K203428.

Conclusion of Table above: The changes of the proposed modified device Ziehm Vision RFD C-arm described in the table do not change the fundamental control mechanism, operating principle, energy type, or intended use found on predicate device and supports substantially equivalents to the predicate device Ziehm Vision RFD (K203428) in accordance with its labeling.

Safety and Performance: The proposed Ziehm Vision RFD 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 Vision RFD is based on direct modifications to cleared predicate device Ziehm Vision RFD (K203428).

The design of the modified Ziehm Vision RFD 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.

Performance testing confirmed that the modified Ziehm Vision RFD 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 Vision RFD (K203428) 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 RFD 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 Vision RFD C-arm image quality, safety and effectiveness supports a determination of substantial equivalence to the predicate device Ziehm Vision RFD (K203428).

Compliance to FDA Guidance and Standards

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 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 3.2, 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 Vision RFD 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 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 RFD results in a comparable patient care to the Predicate device Ziehm Vision RFD (K203428) and fulfils the requirements as stated by the intended use. Therefore, Ziehm Imaging GmbH believes the Ziehm Vision RFD C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Ziehm Vision RFD (K203428).

Conclusion Ziehm Imaging GmbH considers the Ziehm Vision RFD to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Vision RFD (K203428) in accordance with its labeling.