Ziehm Imaging GmbH
% Mr. Steve Seeman
Director of Regulatory Affairs and Quality Assurance
Ziehm-Orthoscan, Inc.
14555 N. 82nd Street
SCOTTSDALE AZ 85260

March 17, 2021

Re: K203428
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: February 15, 2020
Received: February 24, 2020

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 T. Mills, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203428

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.

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K203428

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

March 11, 2020

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

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Primary Contact Person Agent:	Steve Seeman Director of Regulatory Affairs and Quality Assurance Ziehm-Orthoscan, Inc. 14555 N 82nd St Scottsdale AZ, 85260
Secondary Contact Person:	Stefan Fiedler Director QM/RA Ziehm Imaging GmbH Phone: + 49.911. 2172-219 Fax: +49.911.2172-390
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:	K132904 - Ziehm Vision RFD
Decision Date:	12/05/2013
Regulation:	21CFR 892.1650
Regulation Description Name:	Image-intensified fluoroscopic x-ray system
Product Code:	JAA; OWB; OXO

General Description:

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) Computed tomography x-ray system 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).

Motorization of vertical axis as well as manual or optionally motorized three axes provides the user/operator the option to use manual or motorized linear and rotational movements of the C- Profile for positioning of the imaging components at various angles and distances with respect to the patient using a control interface, Vision Center, Remote Vision Center or remote Position Control Center.

The motorization of the 4 axes provides the user an alternative for visualizing anatomical structures using a variable iso-centric location. The system working with a variable iso-center allows freely selectable positions of patient anatomy. The variable iso-center and distance control ensures that anatomical structures are safely visualized from different angles without re-adjusting the C-arm or moving the patient. The iso-center is not restricted to orbital movements and can hold this iso-center during angulations and vertical travel using the 4 motorized axes.

The Distance Control surface detection integrated around the lower edge of the flat panel detects objects, such as patients. When the flat panel approaches an object, the device reduces speed, slowing the motorized movement. The movement stops immediately before entering a defined safety zone.

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.

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 near MRI systems.

Technology:

The proposed modified device Ziehm Vision RFD C-arm employs the same fundamental control, and scientific technology as that of our predicate device Ziehm Vision RFD C-arm (K132904).

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 RFD C-arm (K132904).

Software architecture design is nearly identical to that of the predicate

	device Ziehm Vision RFD C-arm (K132904). With modification of the software to support functionality, image processing applications related to the optional device specific features. The primary modifications of the C-Arm include a 30 kW generator using the same housing, x-ray tube, and very similar design while keeping the same dimensions as the predicate Ziehm Vision RFD (K132904), new pre-filter and low absorption removable grid, for lower skin entrance dose imaging, improving operator workflow during extended procedures, , Enhanced Vessel Visualization, measurement function, while keeping the same profile of our predicate device Ziehm Vision RFD C-arm (K132904).
Summary of Technological Characteristics:	The comparisons of the predicate devices show the scientific and technology characteristics of the Ziehm Vision RFD are substantial equivalence to that of the predicate device Ziehm Vision RFD (K132904).

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 (K132904)**	**Comparable Properties Substantial Equivalence Discussion**
510(k) Number	Unknown at this time	K132904	-
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	The Ziehm Vision RFD is intended for use in providing medical imaging, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intraoperative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include	Substantially Equivalent

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K132904)	Comparable Properties Substantial Equivalence Discussion
	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.	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 in and around high magnetic fields. 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. The system is not intended for use near MRI systems.	

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K132904)	Comparable Properties Substantial Equivalence Discussion
X-ray Generator			
Maximum Parameter	• Variant 20 kW: max. 20 kW, max. 120 kV, max. 200 mA • Variant 25 kW: max. 25 kW, max. 120 kV, max. 250 mA **Variant 30 kW:** **max. 30 kW @ nominal 100kV** **max. 120 kV,** **max. 300 mA**	• Variant 7.5 kW: max. 7.5 kW, max. 120 kV, max. 75 mA • Variant 20 kW: max. 20 kW, max. 120 kV, max. 200 mA Variant 25 kW: max. 25 kW, max. 120 kV, max. 250 mA	The new proposed device generator (variant 30 kW) has a higher maximum power output. 100 kV @ 300 mA.
Pulsed Fluoroscopy: Operating values	• Variant 20 kW kV range: 40 - 120 kV mA range: 1.5 - 200 mA • Variant 25 kW kV range: 40 - 120 kV mA range: 1.5 - 250 mA **Variant 30 kW** kV range: 40 - **120 kV** mA range: 1.5 – **300 mA**	• Variant 7.5 kW kV range: 40 - 120 kV mA range: 1.5 - 75 mA • Variant 20 kW kV range: 40 - 120 kV mA range: 1.5 - 200 mA Variant 25 kW kV range: 40 - 120 kV mA range: 1.5 - 250 mA	The new generator 30 kW of the new modified proposed device has a higher maximum power output as compared to the Predicate. However, the design and housing are identical.
Pulsed Fluoroscopy: Pulse and Duration	• pulse width: - 20 kW generator: 7 - 40 ms - 25 kW generator: 7 - 40 ms - **30 kW generator: 4 - 40 ms** pulse rate: 50/60 Hz: 1, 2, 4, 8, 12.5, 25 pulse/s	• pulse width: - 7.5 kW generator: 7 - 40 ms - 20 kW generator: 7 - 40 ms - 25 kW generator: 7 - 40 ms pulse rate: 50/60 Hz: 1, 2, 4, 8, 12.5, 25 pulse/s	
Digital Radiography (Snapshot) / Operating Values	• Variant 20kW kV range: 40 - 120 kV mA range: up to 200 mA • Variant 25kW	• Variant 7.5 kW kV range: 40 - 120 kV mA range: up to 75 mA • Variant 20 kW	Although the modified device Ziehm Vision RFD is not identical to the predicate K132904 the general system exposure control technology and

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K132904)	Comparable Properties Substantial Equivalence Discussion
	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**	kV range: 40 - 120 kV mA range: up to 200 mA Variant 25kW kV range: 40 - 120 kV mA range: up to 250 mA	operational functionality are identical in regards to the predicate K132904
Thermal Management	Active cooling	Active cooling	Identical
X-ray Tube			
Tube Type	Rotating anode	Rotating anode	Identical
Beam Limiter/ Collimator			
Collimator System	Asymmetrical Collimator	Asymmetrical Collimator	Identical
Image Detector			
Detector Technology	Variant aSi FPD (8inch; 12inch): • Type: Amorphous Silicon Flat Panel Detector (aSi) • Scintillator: Cesium-Iodide (CsI) Variant CMOS FPD(8inch; 12inch): • Type: CMOS Flat Panel Detector Scintillator: Cesium-Iodide (CsI)	Variant aSi FPD (8inch; 12inch): • Type: Amorphous Silicon Flat Panel Detector (aSi) • Scintillator: Cesium-Iodide (CsI) Variant CMOS FPD(8inch; 12inch): • Type: CMOS Flat Panel Detector • Scintillator: Cesium-Iodide (CsI)	Identical
Anti-Scatter Grids			
Fixed anti-scatter grid	fixed anti-scatter grid: Pb 8/70	fixed anti-scatter grid: Pb 8/70	Identical
optional removable anti-scatter grid	Removable Grid: Pb 8:1 / 70 lines	Removable Grid: Pb 8:1 / 70 lines	Identical
Laser Positioning Device			

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K132904)	Comparable Properties Substantial Equivalence Discussion
Laser Positioning Device on Generator (optional)	Class 2M (IEC 60825-1), 635 nm	Class 2M (IEC 60825-1), 635 nm	Identical
Laser Positioning Device on Image Detector	Class 2M (IEC 60825-1), 635 nm	Class 2M (IEC 60825-1), 635 nm	Identical
Electrical Requirements			
Electrical Requirements	• Power supply: 100-240 V_{AC} (± 10%), 50/60 Hz	• Power supply: 100-240 V_{AC} (± 10%), 50/60 Hz	Identical.
Mechanics			
Mechanical Size weight	Weight and dimensions	Weight and dimensions	Identical
Monitors			
Display Monitor	• 19" Duo flat screen monitors or • 26" color flat screen monitor • 32" UDH single flat screen monitor	• 18" Duo flat screen monitors or • 19" Duo flat screen monitors or • 26" color flat screen monitor	Identical in performance and use.
Monitor Arm	Monitor Cart with fix or articulating monitor arm (option)	Monitor Cart with fix or articulating monitor arm (option)	Identical
Endoscopy Display Option	26'' color flat screen monitor	26'' color flat screen monitor	Identical
User Interface			
Control Elements Touch Panel	Vision Center Remote Vision Center	Vision Center Remote Vision Center	Identical
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	• Cable bound footswitch • optional: Wireless footswitch	Identical
Further X-ray switches	• Radiation button at "Vision Center" • Radiation button at "Remote Vision Center"	• Radiation button at "Vision Center" • Radiation button at "Remote Vision Center"	Identical

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K132904)	Comparable Properties Substantial Equivalence Discussion
Digital Image Processing			
2D imaging	2D Fluorscopic Imaging	2D Fluorscopic Imaging	Identical:
Application-Oriented Anatomical Programs (AOAP)	• Bone: Extremities, Trunk • Heart, Abdomen, Soft • Vascular (option): Extremities, Trunk, Bolus • Urology (option) • Endo (option)	• Bone: Extremities, Trunk • Heart, Abdomen, Soft • Vascular (option): Extremities, Trunk, Bolus • Urology (option) • Endo (option)	Identical
Additional Functions	• Metal • **Enhanced Vessel Visualization (option)** • Reposition • High Quality • Low Dose • Obese Patient	• Metal • Reposition • High Quality • Low Dose • Obese Patient • Motion	The Modified Device Ziehm Vision RFD has additional Enhanced Vessel Detection function to that of the Predicate Ziehm Vision RFD (K132904)
Image Acquisition	• Auto save • Cine loop	• Auto save • Cine loop	Identical
Post-Processing Functions	• Zoom: *3 levels*	• Zoom: 3 levels	Identical
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 • Single frame, Multiframe RSA (road-mapping) • Pixel shift / landmarking	Identical
Anatomical Marking Tool - AMT (option)	• Mark anatomical structures • 2D measurement function	• Mark anatomical structures	The Modified Device Ziehm Vision RFD has additional 2D measurement function within the Anatomical Marking Tool that is similar to that of the Predicate Ziehm Vision RFD
Digital Memory	• Storage capacity	• Storage capacity	Identical
Data	• Radiation Dose	• Radiation Dose	Although not identical.

Model	Modified Ziehm Vision RFD	Predicate Ziehm Vision RFD (K132904)	Comparable Properties Substantial Equivalence Discussion
Organization	Structured Report (RDSR) • Calculated Dose Area Product (DAP) • *DAP value tagged to stored image* • *Air Kerma dose display* • *Air Kerma value tagged to stored image*	Structured Report (RDSR) • Calculated Dose Area Product (DAP)	The new features improve the clinician's ability to obtain more information as to the dose for each image in the radiation structured dose report.
HIPAA	option for HIPAA Security	option for HIPAA Security	Identical
Cybersecurity	Software integrity check	Software integrity check	Identical
DICOM	DICOM 3	DICOM 3	Identical
Inter-operability (options)	• Ziehm NaviPort 2D • Ziehm NetPort (DICOM 3.0 interface) • Generic interface to injector • Video transmission (video connector or wireless video) • Interface for external separate X-ray indication lamp	• Ziehm NaviPort 2D • Ziehm NetPort (DICOM 3.0 interface) • Generic interface to injector • Video transmission (video connector or wireless video) Interface for external separate X-ray indication lamp	Indentical

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 (K132904) 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, **r**ecognized 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 (K132904).

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.

Documentation provided demonstrates compliance of the modified device Ziehm Vision RFD 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 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 (K132904) 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 "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".

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 (K132904).

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)
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 3.1, 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
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

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. 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 RFD results in a comparable patient care to the Predicate device Ziehm Vision RFD (K132904). 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 (K132904).

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 (K132904) in accordance with its labeling.