



February 5, 2024

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

Re: K240099

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: OWB, JAA,OXO
Dated: January 12, 2024
Received: January 12, 2024

Dear Tsvetelina Milanova:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

Sincerely,

A stylized signature of "Lu Jiang" in a cursive font, overlaid on a large, light blue "FDA" logo.

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

Indications for Use

Submission Number (if known)

K240099

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 lumbar 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.

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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510(k) #: K240099

510(k) Summary

Prepared on: 2024-02-05

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Ziehm Imaging GmbH
Applicant Address	Lina-Ammon-Strasse 10 Nuremberg 90471 Germany
Applicant Contact Telephone	+4991166067581
Applicant Contact	Ms. Tsvetelina Milanova
Applicant Contact Email	Zie-Regulatory@ziehm.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Ziehm Vision RFD
Common Name	Mobile Fluoroscopic C-Arm
Classification Name	Image-intensified fluoroscopic x-ray system
Regulation Number	21 CFR 892.1650
Product Code(s)	OWB, JAA; OXO

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231692	Ziehm Vision RFD	OWB

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

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 Ziehm Vision RFD employs the same fundamental control, and substantially equivalent scientific technology as that of our predicate device Ziehm Vision RFD (K231692). Software architecture design is substantially equivalent to that of the predicate Ziehm Vision RFD.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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 lumbar 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.

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Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the predicate and modified device are equivalent.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The predicate and proposed devices have the same technological characteristic. The key modification refers to an updated release of the software, which incorporates an operating system upgrade from Ubuntu 16.04 to Ubuntu 20.04.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

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.

No new tests regarding electrical safety according to ANSI/AAMI ES60601-1 and regarding electromagnetic compatibility according to IEC 60601-1-2 were performed. The device is compliant with both standards. No new tests have been done according to Guidance's "Radio Frequency Wireless Technology in Medical Devices" and "Design Considerations and Premarket Submissions Recommendations for Interoperable Medical Devices". Neither the wireless features nor the interoperable interfaces of the device affect the safety and effectiveness.

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. No new non-clinical image comparison with sets of images with the modified device and the predicate have been performed, the device equivalent regarding image quality. Software testing was performed as required by "Content of Premarket Submissions for Device Software Functions". Cybersecurity testing was performed according to the guidance document, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.