January 21, 2025

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

Re: K243303
Trade/Device Name: Ziehm Vision RFD 3D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: November 22, 2024
Received: November 22, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Radiological 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.

510(k) Number *(if known)*
K243303

Device Name
Ziehm Vision RFD 3D

Indications for Use *(Describe)*
The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D pulsed and continuous fluoroscopic medical imaging for adult and pediatric populations.
The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops 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-Assisted Surgery procedures.
The device is also intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures.
The visualization of such anatomical structures assists the clinician in the clinical outcome.
This device does not support direct radiographic film exposures and is not intended for use in performing mammography.
The system is not intended for use in any 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) #: K243303

510(k) Summary

Prepared on: 2025-01-20

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	Tsvetelina Milanova
Applicant Contact Email	Zie-Regulatory@ziehm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ziehm Vision RFD 3D
Common Name	Image-intensified fluoroscopic x-ray system
Classification Name	Image-intensified fluoroscopic x-ray system
Regulation Number	892.1650
Product Code(s)	OWB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231701	Ziehm Vision RFD 3D	OWB

Device Description Summary

21 CFR 807.92(a)(4)

The device Ziehm Vision RFD 3D is a medical Fluoroscopic X-ray imaging device used to assist trained physicians in the X-ray visualization of anatomical regions of a patient. The system is a non-contact device and is not intended to be in contact with patient to perform its intended use. The system provides X-ray image data by means of X-ray technique while the physician performs medical procedures and stores the image data temporarily.

The Ziehm Vision RFD 3D is intended for use to provide 2D- and 3D-image data specifically but not limited in the field of orthopedics, traumatology and oral and maxillofacial surgery. Furthermore it is intended for use specifically but not limited to the imaging of soft tissues.

The modified subject device Ziehm Vision RFD 3D consists of two physical elements. The first referred to as the "C-Arm" or Mobile Stand (MS) because of its wheeled base and C-profile shaped image gantry; the second is referred to as the Monitor Cart (MC) because it provides real-time monitor displays for visualization and records of patient anatomy.

The modified Ziehm Vision RFD 3D employs the same fundamental control, and substantially equivalent scientific technology as that of our predicate device Ziehm Vision RFD 3D (K231701). Software architecture design is substantially equivalent to that of the predicate Ziehm Vision RFD 3D.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D pulsed and continuous fluoroscopic medical imaging for adult and pediatric populations.

The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops 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-Assisted Surgery procedures.
The device is also intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures.
The visualization of such anatomical structures assists the clinician in the clinical outcome.
This device does not support direct radiographic film exposures and is not intended for use in performing mammography.
The system is not intended for use in any MRI environments.

Indications for Use Comparison

21 CFR 807.92(a)(5)

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

Technological Comparison

21 CFR 807.92(a)(6)

The key modification refers to an software update to software version 7.10.0, which incorporates the 2k imaging chain "QuantumStream", along with the corresponding new "Image Insights" overlay, the integration of the optional EndoNaut Aorto Iliac (AI) Workflow Integration by Therenva (K222070), the PCCplus (Position Control Center plus), optional OR table controls, the new 'Adult HQ' body size for the '3D' operating mode as well as further 3D visualization improvements.
The predicate Ziehm Vision RFD 3D (K231701) and modified Ziehm Vision RFD 3D share substantially equivalent design controls, design, technology, functionality and have identical Indications for Use (IFU).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The design of the modified Ziehm Vision RFD 3D 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.

New tests regarding electromagnetic compatibility according to IEC 60601-1-2 were performed and the modified device including option Position Control Center plus is compliant with this standard.

The modified Ziehm Vision RFD 3D 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.

Software and cybersecurity testing was performed as required by "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

The image quality testing was performed with anthropomorphic as well as motion-induced phantoms for the analysis and comparison with the predicate system. Anthropomorphic phantoms so-called "sectional phantoms" were used and are constructed with a natural human skeleton cast inside a proprietary urethane material that has the same effective atomic number as the body's soft tissue. The image comparison between the system settings of the predicate device and the optimized system settings (including 'Adult HQ ' body size and 2k imaging chain) of the modified device shows that the image quality acquired with the test device is better or at least equal. Almost all images generated by the test device show more details, improved detectability and are sharper than the corresponding reference images. From a radiological point of view the image quality of the presented images that were acquired fulfil the requirements as stated by the intended use.

After review of the modified device Ziehm Vision RFD 3D risk control assessments, the verification/validation activities which 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. Ziehm Imaging GmbH therefore, believes the modified device Ziehm Vision RFD 3D to be as safe and effective and performs as well as the predicate devices Ziehm Vision RFD 3D (K231701).