July 10, 2023

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

Re: K231701
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: June 12, 2023
Received: June 12, 2023

Dear Mr. 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 (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,

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231701

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 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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510(k) #:

510(k) Summary

Prepared on: 2023-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ziehm Imaging GmbH
Applicant Address	Lina-Ammon-Strasse 10 Nuremberg Bavaria 90471 Germany
Applicant Contact Telephone	0911-66067-219
Applicant Contact	Mr. Stefan Fiedler
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	Interventional Fluoroscopic X-Ray System
Regulation Number	892.1650
Product Code	OWB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202360	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 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.

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.
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Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical for predicate and proposed device.

Technological Comparison

21 CFR 807.92(a)(6)

The predicate and proposed devices have the similar technological characteristic. The key modification pertains 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)

Ziehm Vision RFD 3D is based on the direct modifications to cleared predicate devices Ziehm Vision RFD 3D (K202360); The design changes were completed in accordance with Ziehm Imaging GmbH Quality Management System Design Controls and Engineering, standards compliance, and Verification and Validation testing were successfully conducted on the Ziehm Vision RFD 3D. Further compliance testing for the modified device to all FDA requirements as stated in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" as applicable including software requirements and software risk hazards was done. Tests performed on the Ziehm Vision RFD 3D, demonstrated that the device is safe and effective, performs comparably to the predicate devices, and substantially equivalent to the predicate devices.