March 17, 2025

Ziehm Imaging GmbH
℅ Cornelia Schildbach
Specialist Regulatory Affairs
Lina-Ammon-Strasse 10
Nuremberg, 90471
GERMANY

Re: K243646
Trade/Device Name: Ziehm Solo FD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: November 25, 2024
Received: November 26, 2024

Dear Mrs. Schildbach:

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)*
K243646

Device Name
Ziehm Solo FD

Indications for Use *(Describe)*

The Ziehm Solo FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging.
The device provides contactless fluoroscopic image capture, temporarily storing, and display of digital subtraction, and acquisition of cine loops during diagnostic, interventional and surgical procedures. Examples of clinical application may include pediatric, cholangiography, endoscopic, urologic, lithotripsy, orthopedic, neurologic, vascular, cardiac, angiographic, critical care, and emergency room fluoroscopy 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K243646

510(k) Summary

Prepared on: 2025-02-17

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	+4991166067258
Applicant Contact	Mrs. Cornelia Schildbach
Applicant Contact Email	Zie-Regulatory@ziehm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ziehm Solo FD
Common Name	Image-intensified fluoroscopic x-ray system
Classification Name	Image-intensified fluoroscopic x-ray system
Regulation Number	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
K234109	Ziehm Solo FD	OWB

Device Description Summary

21 CFR 807.92(a)(4)

Ziehm Solo FD uses X-ray imaging technology to visualize the human anatomy. The X-ray tube in the generator produces X-rays that penetrate the patient and then hit a special detector that converts them into digital images. This is done under the control of the user and at the direction of a physician who determines the specific clinical procedure. This visualization assists the physician in localizing pathological areas or during surgical procedures. The device enables real-time image acquisition as well as visualization of in vivo surgical procedures and post-operative results.

The Ziehm Solo FD consist of one mobile unit, the Mobile Stand. Optionally the device can be ordered with a Viewing Station (Monitor Cart). The Mobile Stand incorporates a small compact design making the positioning of the C-arm in relation to the patient easier for the operator. The generator with X-ray tube, advanced heat management system, X-ray control and collimators are assembled in one housing in a mono-block generator. The system control is handled via CAN BUS control system.

The mechanical C-Profile supports the generator, the flat panel detector and an integrated laser positioning device. The optional available Viewing Station (Monitor Cart) provides a remote touch Solo Center that duplicates the touch Solo Center mounted on the Mobile Stand.

The comparison of the predicate device and the modified device shows that the scientific and technical characteristics of the Ziehm Solo FD are substantially equivalent as those of the Ziehm Solo FD predicate device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Ziehm Solo FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging.

The device provides contactless fluoroscopic image capture, temporarily storing, and display of digital subtraction, and acquisition of cine loops during diagnostic, interventional and surgical procedures. Examples of clinical application may include pediatric, cholangiography, endoscopic, urologic, lithotripsy, orthopedic, neurologic, vascular, cardiac, angiographic, critical care, and emergency room fluoroscopy 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 substantial equivalent. Only the wording has been updated.

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. In addition to the already introduced 8 inch IGZO flat panel detector, the modified Ziehm Solo FD offers an 12 inch IGZO panel. The manufacturing technology (IGZO, Indium-Gallium-Zinc-Oxide) of both detectors 8 inch and 12 inch as well as the image quality are equivalent.
The predicate Ziehm Solo FD (K234109) and the modified Ziehm Solo FD share substantially equivalent design controls, design, technology, functionality and have substantially equivalent Indications for Use.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The design of the modified Ziehm Solo FD 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 text.

The modified Ziehm Solo FD 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, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-43 and IEC 60601-2-54.

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 2k imaging chain) of the modified device shows that the image quality acquired with the test device is better or at least equal. The same applies to images acquired with newly introduced 12 inch flat panel detector. 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.

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

Cybersecurity testing comprises vulnerability scanning, penetration testing an static code analysis. Vulnerability scanning has been performed on the devices SBOMs and additionally using Tenable Nessus. The findings have been assessed and found acceptable. Two separate penetration tests have been conducted and displayed a good cybersecurity posture of the device. The results from the static code analysis indicate some code locations that might benefit from a code adaption, but no stability nor any security issue could be identified that would require immediate action. The points for improvement have been noted for subsequent software releases. Overall the testing activities demonstrate a good level of cybersecurity for the device, complying with the FDA requirements.

After review of the modified device Ziehm Solo FD risk control assessment, the verification/validation activities which successfully confirmed device requirements have been fulfilled, system functionality is consistent with the user needs, intended use, and performs as designed and raises no new questions regarding either safety or effectiveness. Ziehm Imaging GmbH therefore believes the modified device Ziehm Solo FD to be substantial equivalent to the predicate device Ziehm Solo FD (K234109).