January 14, 2026

Ziehm-Orthoscan, Inc.
% Kevin Bridgman
VP of Regulatory Affairs and Quality Assurance
14555 N. 82nd St.
SCOTTSDALE, AZ 85260

Re: K252579
Trade/Device Name: Orthoscan TAU MVP Mini C-Arm System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA, MQB, HRX, GCJ
Dated: December 15, 2025
Received: December 15, 2025

Dear Kevin Bridgman:

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, 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

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)*
K252579

Device Name
Orthoscan TAU MVP Mini C-Arm System

Indications for Use *(Describe)*
The Orthoscan TAU MVP system is designed to provide physicians with general fluoroscopic visualization, using pulsed or continuous fluoroscopy, of a patient including but not limited to, diagnostic, surgical, and critical emergency care procedures for patients of all ages including pediatric populations when imaging limbs/extremities, shoulders, at locations including but not limited to, hospitals, ambulatory surgery, emergency, traumatology, orthopedic, critical care, or physician office environments.
The scope used with Orthoscan TAU MVP system is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of interior cavity joints and other body cavities through a natural or surgical opening.

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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Traditional 510(k) Summary
Traditional 510 (k) Premarket Notification Submission- Ziehm-Orthoscan, Inc.
Orthoscan TAU MVP Mini C-Arm System (K252579)

Submitter: Ziehm-Orthoscan, Inc.
14555 N 82nd St.
Scottsdale, AZ 85260
Phone: (480) 503-8010
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Primary Contact: Kevin Bridgman; Kevin.bridgman@ziehm-orthoscan.com
Secondary Contact: TuAnh Ngo; tuanh.ngo@ziehm-orthoscan.com
Date: January 14, 2026

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

Device Trade Name: Orthoscan TAU MVP Mini C-Arm System

510(k) Number: K252579

Common/Usual Names: Fluoroscopic X-Ray System, Mobile Mini Mobile C-arm, Mini C-arm, Arthroscope, Endoscope and Accessories

Regulation: 21 CFR 892.1650

Device Class: Class II

Regulation Names: Image-intensified fluoroscopic x-ray system

Device: Image-Intensified Fluoroscopic X-ray System, Mobile
Product Codes: OXO, JAA, MQB, HRX, GCJ

Primary Predicate: Orthoscan TAU Mini C-Arm
510(k) Number: K250587
Regulation: 21 CFR 892.1650
Device Class: Class II
Regulation Names: Image-intensified fluoroscopic x-ray system
Product Code: OXO, JAA, MQB

Secondary Predicate: MIDASVu
510(k) Number: K243020

General Description:
The proposed Orthoscan TAU MVP (Multi Viewing Platform) Mini C-Arm system models 1000-0022, 1000-0023 retain identical function as the predicate Orthoscan TAU Mini C-Arm (250587) as a mobile fluoroscopic mini C-arm system that provides fluoroscopic images of patients of all ages during diagnostic, treatment and surgical procedures involving anatomical regions such as but not limited to that of extremities, limbs, shoulders and knees and hips. The system consists of C-Arm support attached to the image workstation.
The proposed Orthoscan TAU MVP Mini C-Arm system models 1000-0022, 1000-0023 represent a modification of our presently legally marketed devices Orthoscan TAU Mini C-Arm (K250587). The proposed Orthoscan TAU MVP Mini C-Arm System will consist of the Orthoscan TAU Mini C-Arm X-ray System with additional arthroscopic imaging capability to further standardize the product platform by incorporating components currently available in predicate devices into the Orthoscan TAU MVP system.

The proposed new Orthoscan TAU MVP system is a collaborative effort to display the fluoroscopic and arthroscopic image concurrently.

The proposed modifications to the predicate encompass the incorporation of hardware and software from MIDASVu arthroscopic imaging system reusable tablet (K243020) utilizing a modified mechanical design to incorporate a video processing unit imaging control board, umbilical cord and arthroscopic imaging system comprised of sterile, single-use scopes (K243020). The scopes include camera and image capture features with LED light source. The distal tip of the scopes contains the camera, illumination, and imaging optics. The scopes are available in three lengths: 60mm, 90mm, and 120mm. The scopes and the TAU MVP Mini C-Arm system work in concert as a system to acquire, display and record an intra-articular image as well as store images and video taken during the procedure.

For both the predicate TAU (K250587), MIDASVu (K243020) and proposed device Orthoscan TAU MVP, the following are unchanged: identical C-arm support and mechanical connections, balancing, locking, rotations, work-station platform, monitor display and main user interface controls, touch screen interface, selectable imaging, X-ray technique control, entry of patient information, wired or wireless footswitch operation, interface connection panel and DICOM fixed wire and wireless network interfaces, single use disposable scope, optics and components, mechanical dimensions and materials, imaging optics and connection into system. The proposed Orthoscan TAU MVP device uses a similar and substantially equivalent arthroscopic image acquisition and display type.

Indications for Use:
The Orthoscan TAU MVP system is designed to provide physicians with general fluoroscopic visualization, using pulsed or continuous fluoroscopy, of a patient including but not limited to, diagnostic, surgical, and critical emergency care procedures for patients of all ages including pediatric populations when imaging limbs/extremities, shoulders, at locations including but not limited to, hospitals, ambulatory surgery, emergency, traumatology, orthopedic, critical care, or physician office environments.
The scope used with Orthoscan TAU MVP system is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of interior cavity joints and other body cavities through a natural or surgical opening.

Indications for Use Comparison:
The proposed Orthoscan TAU MVP Mini C-Arm System has the same indications for use as the predicate devices Orthoscan TAU (K250587) and MIDASVu (K243020).

Technology:
The changes to the proposed device Orthoscan TAU MVP Mini C-Arm System represent a modification of our presently legally marketed device Orthoscan TAU Mini C-Arm (K250587). With the introduction of the MIDASVu arthroscopic imaging system comprised of sterile, single-use scopes (K243020), arthroscopic imaging capability is established to further standardize the product platform by incorporating features currently available in predicate devices into the proposed Orthoscan TAU MVP.

Summary of Technological Characteristics:
The comparisons of the proposed Orthoscan TAU MVP Mini C-Arm demonstrate that the scientific and technology characteristics indicate substantial equivalence to the predicate device Orthoscan TAU Mini C-Arm (K250587) and MIDASVu (K243020).

Adverse Effects on Health:
The proposed Orthoscan TAU MVP's potential radiation, mechanical, and electrical hazards are identified and analyzed as part of risk management and controlled by meeting the applicable CDRH 21 CFR subchapter J performance requirements, Recognized Consensus Standards, designing and manufacturing under Ziehm-Orthoscan, Inc. 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.

Non-Clinical Testing Summary:
Verification and Validation including hazard mitigations executed resulted in demonstrated system that met Design Input and user needs. The device was tested by certified test laboratory resulting in device being certified compliant with IEC 60601-1 ED 3.2 series, including IEC 60601-2-54 and IEC 60601-2-28. Further, the device met all applicable sections of 21 CFR Subchapter J performance standards. The proposed Orthoscan TAU MVP Mini C-Arm 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

The Orthoscan TAU MVP system arthroscopic imaging underwent non-clinical testing to confirm safety, effectiveness, and performance. Electrical safety and EMC testing met IEC 60601 standards, while software validation ensured intended functionality. Software and cybersecurity measures were validated. Results demonstrate the device is as safe and effective as the predicate for its intended use.

Ziehm-Orthoscan, Inc. conducted testing using a leading industry software utility to provide objective image quality statistical analysis of camera systems and compare the displayed arthroscopic image presented by the Orthoscan TAU MVP system to the predicate IntraVu TabletVu display system. Sharpness, color analysis and signal to noise were evaluated and showed that the Orthoscan TAU MVP system performs with equivalent or better arthroscopic image quality when compared to than the predicate IntraVu TabletVu.

Additionally, human factors and usability validation testing was conducted in accordance with IEC 62366-1 and FDA human factors guidance to confirm that intended users can safely and effectively operate the device. The usability validation evaluated representative clinical workflows, including standard fluoroscopic operation, arthroscopic imaging, and dual-mode operation combining fluoroscopy and arthroscopy, to ensure that mode transitions, user interface controls, and system feedback are clear and intuitive. Testing demonstrated that critical tasks, including those performed during dual-mode operation, can be completed without use-related errors that could result in unacceptable risk, and that identified hazards are adequately mitigated through the user interface design, labeling, and training.

Image latency testing was also performed to evaluate absolute end-to-end display latency in fluoroscopy-only, arthroscopy-only, and dual-mode operation, ensuring latency remained below industry-standard criteria established in the scientific literature. Comparative latency was also assessed between fluoroscopy-only mode and the fluoroscopy function in dual-mode operation, and between arthroscopy-only mode and the arthroscopy function in dual-mode operation, to verify that dual-mode operation did not introduce additional risk. Testing was conducted under representative and worst-case operating conditions. Results demonstrated that display latency remained within established acceptance criteria and dual mode functionality did not introduce unacceptable risk related to visualization delay, hand–eye coordination, or procedural workflow.
Therefore, Ziehm-Orthoscan, Inc. believes the proposed Orthoscan TAU MVP Mini C-arm safety and effectiveness to be substantially equivalent to that of the predicate device Orthoscan TAU (K250587) and MidasVu (K243020).

Substantial Equivalence Conclusion:

The changes and differences of the proposed Orthoscan TAU MVP Mini C-arm system do not change the control mechanism, operating principle, energy type, or intended use found on the predicate devices Orthoscan TAU Mini C-Arm (K250587) and MIDASVu (K243020).

Ziehm-Orthoscan, Inc. considers the proposed Orthoscan TAU MVP Mini C-Arm System to be as safe as effective and performs substantially equivalent to the predicate devices Orthoscan TAU Mini C-Arm (K250587) and MIDASVu (K243020) in accordance with its labeling.