January 14, 2025

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

Re: K243452
Trade/Device Name: Orthoscan VERSA Mini C-Arm
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA, MQB
Dated: November 21, 2024
Received: November 21, 2024

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

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)*
K243452

Device Name
Orthoscan VERSA Mini C-Arm

Indications for Use *(Describe)*
The Orthoscan VERSA Mini C-arm X-ray 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**Traditional 510(k) Summary**
**Traditional 510 (k) Premarket Notification Submission- Ziehm-Orthoscan, Inc. VERSA Mini C-Arm**

**Submitter: Ziehm-Orthoscan, Inc.**
**14555 N 82nd St.**
**Scottsdale, AZ 85260**
**Phone: (480) 503-8010**
**Fax: (480) 503-8011**
**Primary Contact: Kevin Bridgman; Kevin.bridgman@ziehm-orthoscan.com**
**Secondary Contact: TuAnh Ngo; tuanh.ngo@ziehm-orthoscan.com**
**Date: October 1, 2024**

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

| | |
|---|---|
| Device Trade Name: | Orthoscan VERSA Mini C-Arm |
| 510(k) Number: | K243452 |
| Common/Usual Names: | Fluoroscopic X-Ray System, Mobile Mini Mobile C-arm, Mini C-arm |
| Device Class: | Class II |
| Classification(s): | 21CFR 892.1650 |
| Classification Names: | Image-intensified fluoroscopic x-ray system |
| Product Code: | OXO, JAA, MQB |

| | |
|---|---|
| Primary Predicate: | Orthoscan TAU Mini C-Arm |
| 510(k) Number: | K213113 |
| Classification(s): | 21CFR 892.1650 |
| Device Class: | Class II |
| Classification Names: | Image-intensified fluoroscopic x-ray system |
| Product Codes: | OXO, JAA, MQB |

| | |
|---|---|
| Secondary Predicate: | Orthoscan Mobile DI Mini C-Arm |
| 510(k) Number: | (K113708) |
| Classification(s): | 21CFR 892.1650 |
| Device Class: | Class II |
| Classification Names: | Image-intensified fluoroscopic x-ray system |
| Product Codes: | OXO, JAA, MQB |

**General Description:**
The proposed modifications to Ziehm-Orthoscan, Inc. VERSA Mini C-Arm series (which we will refer to internally and in this submittal as Orthoscan VERSA, for distinction from predicate Orthoscan TAU and Orthoscan Mobile DI) retain identical function as the predicate TAU Mini C-arm (K2131130) and predicate Mobile DI (K113708) 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. The system consists of C-arm support attached to the image workstation.

The changes to the Orthoscan VERSA Mini C-arm X-ray system represent a modification of our presently legally marketed device Orthoscan TAU Mini C-Arm K213113 and Orthoscan Mobile DI Mini C-arm (K113708). The proposed modifications to the predicate encompass the implementation of a LINUX based operating system upgrade from Ubuntu version 16.04 to Ubuntu version 20.04 and related software revisions, modification to the mechanical design to further facilitate desk top use, revisions to

generator printed circuit board to improve power management efficiency, implementation of an alternate generator radiation shielding material to reduce environmental impact of lead and an update to wireless footswitch communication protocol.

The proposed device replicates the features and functions of the predicate devices without impacting image clarity or dose levels.

For both the predicate and proposed device, the following are unchanged; C-arm support of flat panel detector, generator and x-ray controls, 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.

**Indications for Use:**
The Orthoscan VERSA Mini C-arm X-ray 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.

**Indications for Use Comparison:**
The proposed modifications to Ziehm-Orthoscan, Inc. VERSA Mini C-Arm series do not change the indications for use. The indications for use are the same as the predicate device TAU (K213113) and Mobile DI (K113708) Mini C-Arms.

**Technology:**
The changes to the proposed device Orthoscan VERSA Mini C-arm X-ray systems represent a modification of our presently legally marketed device Orthoscan TAU Mini C-Arm (K213113) and Orthoscan Mobile DI (K113708). With the introduction of a Linux based operating system (OS) upgrade from Ubuntu 16.04 to Ubuntu 20.04, an open source highly secure OS, cybersecurity controls are improved, image quality is maintained or improved, and a capability is created for future expansions of the proposed VERSA device. Modification to the predicate Orthoscan Mobile DI model 1000-0005 (K113708) mechanical design further facilitates desk top use by relocating the image processing printed circuit card, power manager circuit card and related hardware and cabling behind the display electronics within the monitor display assembly. Revisions to generator printed circuit board improve power management efficiency and implementation of an alternate generator radiation shielding material reduces environmental impact of lead. Updating the communication protocol of wireless footswitch from fixed pairing method to code-hopping method maintains state of the art wireless communications and perpetuate free operator movement with fewer cables in the way.

**Summary of Technological Characteristics:**
The comparisons of the proposed modifications to Ziehm-Orthoscan, Inc. VERSA Mini C-Arm demonstrate that the scientific and technology characteristics indicate substantial equivalence to the predicate device Orthoscan TAU Mini C-Arm (K213113) and Orthoscan Mobile DI Mini C-arm (K113708).

**Adverse Effects on Health:**
The proposed modified Ziehm-Orthoscan, Inc. VERSA Mini C-arm's potential radiation, mechanical, and electrical hazards are identified and analyzed as part of risk management and controlled by meeting the applicable CDRH 21CFR 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 and usability testing 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 60601-1 ED 3.2 series, including IEC 60601-2-54. Further, the device met all applicable sections of 21 CFR Subchapter J performance standards.
The proposed modified Ziehm-Orthoscan, Inc. VERSA 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 and usability testing

Performance bench testing included non-clinical testing methods specific to guidance for submission of 510(k)s for Solid State X-Ray Imaging Devices (SSXI); demonstrating system and imaging performance. Non-clinical image and dose lab testing were employed. Anthropomorphic (PMMA material) phantoms and anatomical simulation phantoms were employed and images were taken by both the proposed VERSA and the predicate device Orthoscan TAU (K213113). Numerous image comparison sets were taken, and a Radiologist performed an assessment of individual images arranged in groups of image sets. His conclusion was that the image quality at same or similar patient dose rates will result in equivalent or slight improvement in patient care (images) for the proposed modified VERSA device over the predicate device. Therefore, Ziehm-Orthoscan, Inc. believes the VERSA Mini C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Orthoscan TAU (K213113) and Orthoscan Mobile DI (K113708).

Usability testing included confirming the usability specifications of the proposed modified Ziehm-Orthoscan, Inc. VERSA Mini C-Arm, as well as the user interface of the device, especially the interfaces that have changed since the predicate devices. Usability testing concluded that there were no previously unknown use errors or hazardous situations and no unacceptable residual risks due to the changes in user interface from the predicate device Orthoscan TAU (K213113) and Orthoscan Mobile DI (K113708).

**Summary of Clinical Test Data:**
Ziehm-Orthoscan, Inc. VERSA mobile fluoroscopic Mini C-arm system did not require live human clinical studies to support substantial equivalence in accordance with the related guidance documents, Premarket Assessment of Pediatric Medical Devices May 24, 2014 and Pediatric Information for X-ray Imaging Device Premarket Notifications Nov 28, 2017.

Therefore, Ziehm-Orthoscan, Inc. conducted a lab test image comparison study employing the use of anthropomorphic phantoms in establishing substantial equivalence based on the modifications to the proposed device and the bench data taken with Ziehm-Orthoscan, Inc. VERSA Mini C-Arm in comparison to the predicate Orthoscan TAU Mini C-Arm (K213113).

**Substantial Equivalence Conclusion:**
The changes and differences of the proposed Ziehm-Orthoscan, Inc. VERSA Mini C-Arm described do not change the control mechanism, operating principle, energy type, or intended use found on the predicate device Orthoscan TAU Mini C-Arm (K213113) and Orthoscan Mobile DI Mini C-arm (K113708).

Ziehm-Orthoscan, Inc. considers the proposed modified VERSA Mini C-arm to be as safe, as effective, and performs substantially equivalent to the predicate device Orthoscan TAU Mini C-arm (K213113) and Orthoscan Mobile DI Mini C-arm (K113708) in accordance with its labeling.