Ziehm Imaging GmbH
% Steve Seeman
Director of Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.
6280 Hazeltine National Drive
ORLANDO, FL 32822

November 20, 2019

Re: K190497
Trade/Device Name: Ziehm 8000
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: October 16, 2019
Received: October 18, 2019

Dear Steve Seeman:

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 post-marketing 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190497

Device Name
Ziehm 8000

Indications for Use *(Describe)*
The Ziehm 8000 mobile C-arm is intended for use in providing medical imaging for general populations. 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 or guidance procedures requiring X-ray imaging both inside and outside the operating room. Examples of clinical application may include cholangiography, endoscopic, urologic, lithotripsy, cardiac, orthopedic, neurologic, vascular, pain management, angiographic, critical care, and emergency room fluoroscopy procedures.
This device does not support direct radiographic film exposures and is not intended for use in performing mammography.

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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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Oct 06, 2019

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

Submitter Address:	Ziehm Imaging GmbH Donaustrasse 31 90451 Nuremberg Germany
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Device (Trade Name):	Ziehm 8000
510(k) Number:	unknown
Common /Usual Names:	Mobile Fluoroscopic C-Arm
Regulation number:	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	Interventional fluoroscopic x-ray system
Product Code:	OWB, JAA, OXO
Predicate Device:	Ziehm Quantum (K051064)
Regulation number:	21CFR 892.1650
Regulation Description:	Image-intensified fluoroscopic x-ray system
Device:	Interventional fluoroscopic x-ray system
Product Code:	OWB, JAA, OXO

General Description:

The Ziehm 8000 mobile fluoroscopy system is comprised of a mobile stand with a C-Profile shaped support with both a mono-block high voltage generator assembly and Image Intensifier. These attach to either end of a C-Profile providing a fixed SID. The device performs 2D medical imaging using 4 axes of manual movement and one vertical axes of motorized movement. A user keyboard provides for concise user selectable anatomical programs and X-ray technique control. Integrated high-resolution flat panel display monitors directly mounted on the monitor cart providing the clinician with a precise angle for visualization of live fluoroscopic images of the patient's anatomy. This visualization helps to localize regions of pathology for surgical procedures. The mobile stand supports a cable bound fluoroscopic footswitch. The optional interface panel of the Ziehm 8000 provides connection of peripheral devices such as external monitors, thermal video printers, and image storage devices (USB, DVD) and DICOM fixed wire and wireless network interfaces.

Intended Use

The Ziehm 8000 is a mobile C-arm providing image data by means of a non-contact noninvasive x-ray technique during medical procedures and stores them

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temporarily.

The system can be used for all medical indications where fluoroscopy is required.

The system is intended for use with human beings of any age. It is the physician's responsibility to decide whether to use the system with infants, children and adipose patients.

The system is intended for use with human bodies covering structures such as but not limited to the following, e.g. organs, tissue, bones, implants depending on the medical indication.

Indications for Use:

The Ziehm 8000 mobile C-arm is intended for use in providing medical imaging for general populations. 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 or guidance procedures requiring X-ray imaging both inside and outside the operating room. Examples of clinical application may include cholangiography, endoscopic, urologic, lithotripsy, cardiac, orthopedic, neurologic, vascular, pain management, angiographic, critical care, and emergency room fluoroscopy procedures.

This device does not support direct radiographic film exposures and is not intended for use in performing mammography.

Technology:

The proposed modified device Ziehm 8000 C-arm employs the same fundamental control, and scientific technology as that of our predicate device Ziehm Quantum C-arm (K051064).

The radiation control, X-Ray monoblock generator, power supplies as well as our advanced imaging system are very similar to the predicate device Ziehm Quantum C-arm (K051064).

Software architecture design is nearly identical to that of the predicate device Ziehm Quantum C-arm (K051064)

with modification of the software to support, lower dose functionality, processing applications related to the optional low dose range, image, Variable beam limiting device, and device specific features.

The primary modifications of the C-Arm include a larger but virtually the same medical grade Image receptor as that of the predicate device Ziehm Quantum C-arm (K051064), virtual beam limiting device for precise collimating to anatomical structures, new pre-filter for lower skin entrance dose imaging, incorporation of mechanical design improvements in the C-Arm and mobile workstation balancing, locks, and maneuverability improving operator workflow during extended procedures while keeping the essential profile of our predicate device Ziehm Quantum C-arm (K051064)

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Summary of Technological Characteristics:

The comparisons of the technological characteristics of the proposed device Ziehm 8000 C-Arm to that of the predicate device demonstrates that the scientific and technology characteristics are substantial equivalence to the predicate device Ziehm Quantum C-arm (K051064)

Differences Features/Technology	**Subject Device Ziehm 8000**	**Predicate Device Quantum (K051064)**	**Comparison to Predicate, Comments to Differences**
			The new Ziehm 8000 and the predicate Ziehm Quantum (K051064) share the same general design of the Mobile Stand. The new Ziehm 8000 in comparison to the predicate has a monitor cart (workstation) which supports the imaging and display system. Functionality is essentially the same for imaging and display. They also share a substantial equivalence with regard to but not limited to the intended use, operational functionality of imaging, use of a mono block generator, radiation dose control, user interface control keyboards, 2D imaging acquisition, general dimensional features, scientific technologies, safety, and effectiveness. These changes do not raise new safety or effectiveness concerns.
Mobile fluoroscopic c-arm	Yes	Yes	Identical
Product Codes	OWB, OXO, JAA	OWB, OXO, JAA	Identical
Classification	21CFR 892.1650	21CFR 892.1650	Identical

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Mobile stand Control Elements Touch Panel	Control Panel on Mobile Stand:  Control Panel on Monitor Cart: 	Control Panel on Mobile Stand:  **Touch control panel "DeskView" on Mobile Stand:** 	The general user interface of Ziehm 8000 and the predicate is identical. Both devices have a control panel on the Mobile Stand which allows the control of all device functionalities. Quantum has user touch interface which mimics the same functions as the keyboard. These changes do not raise new safety or effectiveness concerns.
Electrical Requirements	• Power supply: 100-240 V_{AC} (± 10%), 50/60 Hz • Current consumption: 100-120 V: 14 A continuous, 22 A short-time 200-240 V: 10 A continuous, 16 A short-time • Max. impedance: 100-120 V: ≤ 0.3 Ω 200-240 V: ≤ 0.6 Ω • Class I equipment, Type B	• Power supply: **120**/240 V_{AC} (± 10%), 50/60 Hz • Current consumption: **12 A continuous, 30 A short-time** • Max. impedance: ≤ 0.6 Ω Class I equipment, Type B	Although not identical the electrical specifications are similar for the predicate and Ziehm 8000. The new device provides the same Class I Equipment, Type B electrical safety. When reviewed by Ziehm this change does not add any additional risk or change the intended or indication for use to predicate. These changes do not raise new safety or effectiveness concerns.
X-ray generator and tube housing assembly monoblock technology	Yes,	Yes	Identical
KV Range 40-110 kV	Yes	Yes	Identical
Max power output	2.2 kW	2.2 kW	Identical
Fluoroscopy: Output	up to 605 W	up to 660 W	Similar output rating of fluoroscopic power These changes do not raise new safety or effectiveness concerns.
Collimator/beam limiter shutters • Collimator Rotation, +/- 90° and Iris Collimator	Yes	Yes	Identical
Virtual collimation	Yes	No	Ziehm 8000 has a new collimator function compared to the

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			predicate Ziehm Quantum K051064. The virtual collimator provides pre location of collimator edge in the image. May help reduce dose. These changes do not raise new safety or effectiveness concerns.
X-ray Image Receptor Size	I.I. Cesium Iodide 23cm	I.I./cesium iodide Ø 23 cm	Identical
Image Detector (Image Intensifier)	Image Intensifier tube Type: Cesium-Iodide (CsI) DQE (IEC): ≥61% Contrast ration: 27:1	Image Intensifier tube Type: Cesium-Iodide (CsI) DQE (IEC): 65% Contrast ration: 30:1	Although they are not identical the predicate and new Device Ziehm 8000 provide Similar image receptor technology These changes do not raise new safety or effectiveness concerns.
I.I. Sizes Magnification Modes	15cm and 10cm	15cm	Predicate Ziehm Quantum K051064 could only provide a single Image receptor size. These changes do not raise new safety or effectiveness concerns.
FPD FOV	Round FOV	Round FOV	Identical
Camera Matrix	1024 x 1024 pixels	768 x 494 pixels	Although the resolution of the Ziehm 8000 provides slightly better image quality Than the predicate. These changes do not raise new safety or effectiveness concerns.
Grayscale:	12 bit (4,096 shades of gray)	12 bit (4,096 shades of gray)	Identical
Removable anti-scatter grid	Yes	No	Although the resolution of the Ziehm 8000 provides slightly better image quality Than the predicate. it was implemented to allow removal to lower skin dose in certain imaging protocols. These changes do not raise new safety or effectiveness concerns.
Image System Display	1k x 1k	1k x 1k	Identical
Recursive Noise Filtering	Yes	Yes	Identical
Image Post Processing	Yes	Yes	Identical

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Post-Processing Functions	• Edge enhancement: 5 levels • Zoom: 6 levels • Image rotation • Windowing and step windowing • Grayscale inversion	• Edge enhancement: 4 levels • Zoom: 2 levels • Image rotation • Windowing/ leveling • Grayscale inversion	Although not Identical the Ziehm 8000 and predicate have similar features of post processing. Ziehm 8000 has an updated range of edge enhancement and digital image magnification as improvement. These changes do not raise new safety or effectiveness concerns.
Digital Memory	• Storage capacity: 150,000 images • Memory matrix: 1,024 x 1,024 pixels • Image matrix: 1,024 x 1,024 pixels Digital image processing: 16 bit	• Storage capacity: up to 10,000 images (option: 20,000 images) • Memory matrix: 1,024 x 1,024 pixels • Image matrix: 1,024 x 1,024 pixels Digital image processing: 16 bit	Although not Identical the Ziehm 8000 image storage capacity is larger the rest of the memory specification are similar in image matrix and image processing of 16 bits. These changes do not raise new safety or effectiveness concerns.
Archiving External Media	• Video Printer (option): paper / film, paper • USB port (option) • DVD/CD-RW drive (option)	• Video printer port • USB port • USB DVD-RW drive	Identical user available option for printer and multi film/paper archiving capabilities.
AERC Dose control system	Yes	Yes	Identical
DICOM functionality including RSDR	Yes	Yes	Identical
TFT Flat Screen Displays	Yes	Yes	Identical
Monitor Cart	Yes	No	Identical
Monitor support	Yes, integrated on monitor cart	Yes, integrated on mobile stand	Identical
Air Kerma meter	• Calculated Air Kerma • Air Kerma rate mGy/min: • Air Kerma Cumulative mGy	• Calculated Air Kerma • Air Lerma Rate mGy/min • Air Kerma cumulative mGy	Identical
Source-Image Receptor Distance (SID)	95 cm	97 cm	Although not identical the SID is very similar and does not raise new safety or effectiveness concerns
Vertical Free Space	75 cm	76 cm	Although free space is not identical to the predicate K190497 the new device

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			Ziehm 8000 does not raise new safety or effectiveness concerns
C-arm Depth	68 cm	68 cm	Identical
Width	80 cm	80 cm	Identical
Length	162 / 184 cm	160 / 182 cm	Identical
Height	174 / 216 cm	170 / 214 cm	Identical
Manually Operated A-Axis (angulation)	+/- 225° (450°)	+/- 225° (450°)	Identical
Manually Operated B-Axis (swiveling)	+/- 10° (20°)	+/- 10° (20°)	Identical
Manually Operated C-Axis (orbital)	-90° / +45° (135°)	-90° / +45° (135°)	Identical
Manually Operated Y-Axis (horizontal)	22 cm	22 cm	Identical
Motor Driven Z-Axis (vertical)	42 cm	**43 cm**	Although Drive Z-Axis is not identical to the predicate K190497 the new device Ziehm 8000 does not raise new safety or effectiveness concerns
Weight	Mobile Stand: max. 286 kg (629lbs) Monitor Cart: max. 122 kg (286lbs)	Mobile & Monitor Support: Max 264 kg (580lbs)	Although not exactly the same they are similar in mechanical weight for the mobile stand portion of the device. These changes do not raise new safety or effectiveness concerns.
Standards met	• ANSI/AAMI ES60601-1:2012 • IEC 60601-1-2:2014 • IEC 60601-1-3:2008 + A1:2013 • IEC 60601-2-43:2010 • IEC 60601-2-54:2009 • IEC 60825-1:2007 ISO 14971:2007	• UL/IEC 60601-1:1995 • IEC 60601-1-1:1995 • IEC 60601-1-2:2001 • IEC 60601-1-3:1994 • IEC 60601-1-4:1999 • IEC 60601-2-7:1998 • IEC 60601-2-28:1993 • IEC 60601-2-32:1994 • IEC 60825-1:2001 ISO 14971:2001	Use of same Standards for both devices

Conclusion of Table Information:

The changes and similarities of the proposed Ziehm 8000 C-arm described in the table do not change the control mechanism, operating principle, energy type, or intended use found on predicate device and supports substantially equivalents to the predicate device Ziehm Quantum (K051064) in accordance with its labeling.

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Adverse Effects on Health:	The proposed Ziehm 8000 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 and general consensus standards, designing and manufacturing under Ziehm Imaging GmbH 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.

Compliance Standards:

Compliance to FDA Guidance and Standards:

Applicable Standards:

FDA/CDRH From 3626 (8/17)	"A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"
21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems as they may apply.

General Consensus Standard

MDSAP	Medical Device Single Audit Program (MDSAP) Please see MDSAP conformance letter in *Volume 009 File 009*.
MDD 93/42/EEC	Annex II of the European Medical Devices Directive (MDD) 93/42/EEC See EC Certificate in *Volume 009 File 011* and EC Declaration of Conformity in *Volume 009 File 013*.
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes Please see Certificate in *Volume 009 File 015*.

FDA recognized Consensus Standards

AAMI/ANSI ES60601-1	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, mod)

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	Date: 2012 Conformance Standard #19-4
IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General Requirements for Safety, Electromagnetic Compatibility Edition 4.0, Date: 2014-02 Conformance Standard #19-8
IEC 60601-1-3	Medical Electrical Equipment, Part 1-3: Radiation Protection in Diagnostic X-ray Equipment Edition 2.1, Date: 2013-04 Conformance Standard #12-269
IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: Usability Edition 3.1, Date: 2013-10 Conformance Standard #5-89
IEC 60601-2-43	Medical electrical equipment, Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures Edition 2.0, Date: 2010-03 Conformance Standard #12-202
IEC 60601-2-54	Medical electrical equipment, Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy Edition 1.1, Date: 2015 Conformance Standard #12-296
IEC 60825-1	Safety of laser products, Equipment Safety, requirements, and user guide Edition 2.0, Date: 2007 Conformance Standard #12-273
ISO 14971	Medical devices - Application of risk management to medical devices Edition 2.0, Date: 2007 Conformance Standard #5-40

Determination of Substantial Equivalence:

Summary Bench Testing

Verification and Validation including hazard mitigations executed resulted in demonstrated system met Design Input and user needs.

The device was tested by the notified test laboratory resulting in device being certified compliant with ANSI/AAMI ES6060-1-1 series, including IEC 60601-2-54. Further device met all applicable sections of 21 CFR Subchapter J performance standards.

The Ziehm 8000 development occurred under our design control processes, software development processes, and overall quality management system. They included but are not limited to,

- Risk Analysis

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- Required reviews
- Design reviews
- Component testing
- Integration testing
- Performance testing
- Safety testing
- Product use testing

Performance bench testing included:
Non-clinical imaging and dose testing methods demonstrated the device capability to provide both reduced dose while maintaining image quality. Further in line with UCM089742- Premarket Assessment of Pediatric Medical Devices May 24, 2014 and UCM 302938- Pediatric Information for X-ray Imaging Device Premarket Notifications Nov 28, 2017. Non-clinical image and dose Lab testing, were employed. Anthropomorphic (PMMA material) phantoms and anatomical simulation phantoms were employed, image comparison sets taken were representative of both the adult and pediatric populations. A Radiologist performed an assessment of individual image sets. Radiologist conclusion, the image quality of the Ziehm 8000 results in a comparable patient care to the Predicate device (K051064). and fulfils the requirements as stated by the intended use. Therefore, Ziehm Imaging GmbH believes the Ziehm 8000 C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Ziehm Quantum (K051064).

Summary of Clinical Test Data:

Ziehm 8000 mobile fluoroscopic C-arm system did not require live human clinical studies to support substantial equivalence in accordance with the FDA guidance Documents, UCM089742- Premarket Assessment of Pediatric Medical Devices May 24, 2014 and UCM 302938- Pediatric Information for X-ray Imaging Device Premarket Notifications Nov 28, 2017.

Therefore, Ziehm Imaging GmbH conducted an 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. Evaluation of the individual images

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arranged in image sets was conducted by a board-certified Radiologist. His conclusion was the image quality combined with a reduced patient dosage will result in a comparable patient care to the Predicate device Ziehm Quantum (K051064).
His comparison of the dose and images provided further evidence in addition to the laboratory performance data that the complete system works as intended and is substantially equivalent to the predicate device

Conclusion:

Ziehm Imaging GmbH considers the Ziehm 8000 to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Quantum (K051064) in accordance with its labeling.