January 26, 2023

Pausch Medical GmbH
% Oliver Eikenberg
Lead Consultant Quality and Regulatory Affairs
Emergo Global Consulting LLC
2500 Bee Cave Road
Building 1, Suite 300
AUSTIN TX 78746

Re: K221949
Trade/Device Name: ADAPTIX 3D Orthopedic Imaging System ("Ortho Device")
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: Class II
Product Code: IZF , MQB
Dated: December 22, 2022
Received: December 27, 2022

Dear Oliver Eikenberg:

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 2023.01.26 17:03:19 -05'00'

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
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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)*
K221949

Device Name
ADAPTIX 3D Orthopedic Imaging System ("Ortho Device")

Indications for Use *(Describe)*
The Ortho Device is intended to generate tomosynthesis images of human anatomy for diagnostic purposes of the hand, elbow and foot in patients of all ages.
The imaging will provide the physician visualized information about anatomical structures to facilitate assessment in orthopedic cases such as:
• Fractures of bones in finger, metacarpus or wrist
• Fractures of foot, ankle or elbow joint
• Arthritis

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) Summary

ADAPTIX 3D Orthopedic Imaging System ("Ortho Device")

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Oliver Eikenberg, PhD Title: Senior Consultant, Quality & Regulatory Affairs, Emergo Group

3. Date Prepared

01/26/2023

4. Device Identification

Trade/Proprietary Name:	ADAPTIX 3D Orthopedic Imaging System ("Ortho Device")
Common/Usual Name:	Tomographic x-ray system
Regulation Number:	§892.1740 Tomographic x-ray system, §892.1680 Stationary x-ray syst
Product Code:	IZF Tomographic x-ray system, MQB solid state x-ray imager
Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

Primary predicate device

Device name:	DR 800 with Tomosynthesis
Regulation Number:	§892.1740 Tomographic x-ray system §892.1650 fluoroscopic, image-intensified x-ray system
Product Code:	IZF Tomographic x-ray system
Subsequent Product Code:	JAA fluoroscopic, image-intensified x-ray system
510(k) number:	K183275
Manufacturer:	Agfa N.V.

Secondary predicate device

Device name:	OrthoScan Mobile DI Mini C-Arm
Regulation Number:	§892.1650 fluoroscopic, image-intensified x-ray system
Product Code:	OXA mobile image-intensified fluoroscopic x-ray system
Subsequent Product Code:	JAA fluoroscopic, image-intensified x-ray system
510(k) number:	K113708
Manufacturer:	ORTHOSCAN, INC.

6. Indications for Use Statement

The Ortho Device is intended to generate tomosynthesis images of human anatomy for diagnostic purposes of the hand, elbow and foot in patients of all ages.
The imaging will provide the physician visualized information about anatomical structures to facilitate assessment in orthopedic cases such as:

- Fractures of bones in finger, metacarpus or wrist
- Fractures of foot, ankle or elbow joint
- Arthritis

7. Device Description

The Ortho Device is a 3D tomographic X-ray device intended to be used to produce radiological images of a specific cross-sectional plane of the body. The device is comprised of a Flat Panel X-ray source combined with a digital detector within a mounting frame, a control unit and a workstation. It is intended to offer 3D imaging of orthopedic structures by using a panel of X-ray sources that construct a 3D tomosynthesis image with the associated reconstruction software from individual images; it is also possible to create synthetic 2D images of the desired anatomy.

The Ortho Device is a portable system that can be mounted on a stand for tabletop applications or on a trolley cart for added mobility with motorized vertical positioning. The C-Arm and Control Unit components are both designed to be carriable by a single person. To allow for the ideal positioning of the anatomy (hand and weight-bearing foot images) in the beam path and to achieve the desired plane of view, the Ortho Device C-Arm can be manually rotated by up to 90°. The central beam is aligned perpendicularly to the image receptor.

The “Ortho Device” was created to fill a diagnostic niche in orthopedic medicine for cost effective and portable imaging for patients and is used, amongst other applications, for 3D-radiographic diagnostic imaging of hand, elbow and foot in orthopedic and radiological practices as well as in emergency departments of hospitals. The Ortho Device results are detailed multi-slice 3D images of patients that allow radiologist interpretation of clinical image data and by this support medical professionals decision-making on human anatomy.

The Ortho Device system is designed to meet the requirements in accordance with relevant sections of 21CFR 1020.30-1020.31.

8. Substantial Equivalence Discussion

The following table compares the Ortho Device to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics between Subject Device and Predicate Devices

Attribute	Primary Predicate Device DR 800 with Tomosynthesis	Secondary Predicate Device OrthoScan Mobile DI Mini C-Arm	Subject Device Ortho Device	DEVICE COMPARISON
Manufacturer	Agfa N.V.	ORTHOSCAN, INC.	Pausch Medical GmbH	n/a
US Premarket Notification	K183275	K113708	K221949	n/a
FDA Product Code	IZF Tomographic X-ray system, JAA image-intensified fluoroscopic X-ray system	OXO Mobile Image-intensified fluoroscopic X-ray system, JAA image-intensified fluoroscopic X-ray system	IZF Tomographic X-ray system, MQB solid state X-ray imager	Similar
Intended Use / Indications for Use	The DR 800 system is indicated for performing dynamic imaging examinations (fluoroscopy and/or rapid sequence) of the following anatomies/procedures: •Positioning fluoroscopy procedures •Gastro-intestinal examinations •Urogenital tract examinations •Angiography It is intended to replace fluoroscopic images obtained through image intensifier technology. In addition, the system is intended for project radiography of all body parts. In addition, the system provides the Agfa Tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-Ray systems. Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. The DR 800 is not intended for mammography applications.	The Orthoscan Mobile DI Mini C-Arm is designed to provide the physician with general fluoroscopic visualization of the patient including, but not limited to, surgical orthopedic procedures and critical and emergency care procedures in hospital, emergency care, critical care or physician office environment.	The Ortho Device is intended to generate tomosynthesis images of human anatomy for diagnostic purposes of the hand, elbow and foot in patients of all ages. The imaging will provide the physician visualized information about anatomical structures to facilitate assessment in orthopedic cases such as: • Fractures of bones in finger, metacarpus or wrist • Fractures of foot, ankle or elbow joint • Arthritis	Similar
Device Components	Flat Panel detector X-ray Generator X-ray table with tube, housing and Collimator MUSICA Acquisition Workstation with Control Panel	Flat Panel detector X-ray Generator X-ray tube and housing Workstation	Flat Panel detector (C-Arm) Board generating High Voltage (C-Arm) Flat Panel Source (C-Arm) Emission Control Board (C-Arm) Acquisition Board (Control Unit) Workstation	Similar design and intended use to OrthoScan and different to DR 800

Attribute	Primary Predicate Device DR 800 with Tomosynthesis	Secondary Predicate Device OrthoScan Mobile DI Mini C-Arm	Subject Device Ortho Device	DEVICE COMPARISON
Flat Panel Detector	Thales Pixium RF4343 FL Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) Scintillator Field Sizes: 43 x 43 cm, 30 x 30 cm, 20 x 20 cm, 15 x 15 cm Resolution: 2840 x 2874 Dynamic Range 16 bit Pixel size 148 µm	CMOS detector Detector size 15 x 12 cm Field of View (full) 13.8 x 10.9cm Resolution 2000 x 1500 Pixel pitch 75 µm	Flat Panel Detector Detector dimensions: 15x11 cm Resolution: 1488 x 1148 ADC Conversion 14 bit Pixel Pitch: 99 µm	Similar design and intended use to OrthoScan and different to DR 800
X-ray Generator(s)	kV range: 40 to 110 kV mA range: 1.5 to 50.8 mA Choice of three models: 50, 65KW, 80 KW	kV range: 40 to 78 kV mA range: 0.040 to 0.160 mA	kV range: 60 kV (fixed) mA range: 0.01 to 0.05 mA	Different
Collimator	Ralco R 302 MLP/A	Fixed Aperture at fixed SID	Fixed Aperture at fixed SID	Similar to OrthoScan but different to DR 800
Software	MUSICA Dynamic MUSICA2 MUSICA3/3+ MUSICA DTS	Orthotouch	Adaptix Software Package (Acquisition & Reconstruction)	Different
Software Image Manipulation Functions	Image acquisition control and display			Same
Software Image file format	DICOM 3.0 File Output			Same
Type of Software Application	Windows-based software application			Same
Panel Interface	Wired or wireless (optional)		Wired (Ethernet)	Similar
Power Source	230 V AC, 50/60 Hz (X-ray table)	AC: 100-230 V , 50-60 Hz	AC: 110 – 240 V, 50Hz/60Hz	Similar
Accessories	Ankle Rest Foot Rest Head Rest	Cart	Trolley (Cart) Foot Rest Patient supporting arm rest	Similar
Protection type and level against electric shock	Class 1			Same
Electrical Safety, Electro-magnetic Compatibility standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-28 IEC 60601-2-54			Same

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Ortho Device and to show substantial equivalence to the predicate devices, Pausch Medical GmbH completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Ortho Device passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate devices.

- In vitro Cytotoxicity testing per ISO 10993-5 – Passed
- Irritation and skin Sensitization testing per ISO 10993-10 – Passed
- Systemic toxicity testing per ISO 10993-11 – Passed
- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Radiation protection testing in diagnostic X-ray equipment per IEC 60601-1-3 – Passed
- Medical Electrical Equipment Usability testing per IEC 60601-1-6 – Passed
- Safety and essential performance testing of X-ray tube assemblies for medical diagnosis and X-ray equipment for radiography and radioscopy per IEC 60601-2-28 and IEC 60601-2-54 -Passed
- Particular electrical testing performance requirements for *Radiation dose documentation* for X-ray equipment *per* IEC 61910-1 and *Digital Imaging and Communications in Medicine (DICOM) per* NEMA PS 3.1 - Passed
- Transportation Testing per ASTM D4169 demonstrates packaging integrity maintained
- Testing for image quality - spatial and contrast resolution, homogeneity, and linearity etc. – Passed
- Evaluation of sample clinical images by radiologists to demonstrate that the device is able to image all intended body parts (fingers, metacarpus/wrist, elbow, foot, ankle)
- Evaluation of sample clinical images by radiologists to demonstrate that the device is able to provide imaging data to help clinician for the assessment of bone fracture and arthritis
- Software verification and validation testing has been completed on a functional level for a Moderate Level of Concern software including system compatibility testing, risk analysis per IEC 62304/FDA Guidance
- Risk Management per EN ISO 14971, all requirements were met and risks reduced as far as possible.

10. Statement of Substantial Equivalence

The Ortho Device has the same indications for use as the predicate devices OrthoScan Mobile DI Mini C-Arm and DR 800 with Tomosynthesis. Any minor differences in the technological characteristics of the subject device when compared to the predicate devices have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate devices, does not raise any new questions of safety and effectiveness. Therefore, the Ortho Device is substantially equivalent to the predicate devices.