November 6, 2025

Adaptix Limited
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MN 55114

Re: K252133
Trade/Device Name: Adaptix Ortho350
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: Class II
Product Code: IZF
Dated: April 24, 2025
Received: September 23, 2025

Dear Prithul Bom:

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)*
K252133

Device Name
Adaptix Ortho350

Indications for Use *(Describe)*
The Adaptix Ortho350 is intended to be used in hospitals, clinics, imaging centers, and/or other healthcare facilities by qualified/trained doctors or technicians on both adult and pediatric subjects.

The Device is intended to generate tomosynthesis images of human anatomy for diagnostic purposes of body extremities, upper/lower limbs, and adjacent anatomy in all routine radiography examinations.

The device is not intended/indicated for use in imaging of the skull, chest, spinal column, hip, shoulder or in mammography applications.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

I. SUBMITTER

Adaptix Limited
Centre for Innovation and Enterprise, University of Oxford, Begbroke Science Park
Woodstock Road, Oxford, OX5 1PF
United Kingdom
Phone: +44 1865 309619
Contact Person: Martin Stofanko
Date Prepared: November 3,
2025

II. DEVICE

Name of Device: Adaptix Ortho350
Common or Usual Name: System, X-Ray, Tomographic
Classification Name: Tomographic x-ray system (21 CFR 892.1740)
Regulatory Class: II
Product Code: IZF

III. PREDICATE DEVICE

Name of Device: ADAPTIX 3D Orthopedic Imaging System ("Ortho Device")
510(k) number: K221949
Manufacturer: Pausch Medical GmbH
Common or Usual Name: System, X-Ray, Tomographic
Classification Name: Tomographic x-ray system (21 CFR 892.1740),
Regulatory Class: II
Product Code: IZF

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The **Adaptix Ortho350** (K252133) is a 3D tomographic X-ray device intended to generate tomosynthesis images of human anatomy for diagnostic purposes of body extremities, upper/lower limbs, and adjacent anatomy in all routine radiography examinations. The device comprises of an Ortho350 C-Arm Assembly and a Control PC. It is also possible to create 2D X-ray images of the desired anatomy.

The **Adaptix Ortho350** device is a portable system that can be placed on a benchtop or the floor or mounted on an optional cart for added mobility. To obtain 3D tomosynthesis images, the relevant area of the patient is positioned against the detector cover then X-rays are emitted from a controlled sequence of locations. The system uses a low-power, monoblock X-ray source with integrated controls and feedback, synchronized electronically with the detector for tomosynthesis image acquisition. The system is operated by an X-ray technologist or suitably qualified healthcare professional using and designed with safety features to only allow X-ray emission when multiple controls are in place.

V. INDICATIONS FOR USE

The **Adaptix Ortho350** is intended to be used in hospitals, clinics, imaging centres, and/or other healthcare facilities by qualified/ trained doctors or technicians on both adult and pediatric subjects.

The Device is intended to generate tomosynthesis images of human anatomy for diagnostic purposes of body extremities, upper/lower limbs, and adjacent anatomy in all routine radiography examinations.

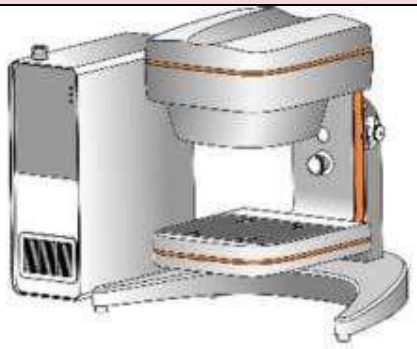
The device is not intended/indicated for use in imaging of the skull, chest, spinal column, hip, shoulder or in mammography applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Device Comparison Summary

The following Table 1 compares the **Adaptix Ortho350** in a side-by-side manner to the predicate device with respect to indications for use, target population, principles of operation, technological characteristics, components and types of verification testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

Table 1 – Comparison of Main Characteristics between Subject Device and Predicate Device

Features/Technology	New Device	Predicate Device	Comparison to Predicate, Comments to Differences
			
Product Codes			
Proprietary Name:	**Adaptix Ortho350**	**Adaptix 3D Orthopedic Imaging System**	N/A
Classification Name	Tomographic x-ray system	Tomographic x-ray system	Same

Classification Product Code	IZF	IZF	Same
Device Class	2	2	Same
Regulation Number	§892.1740	§892.1740	Same
Premarket Review Panel	Radiology	Radiology	Same
Registered Establishment Name	Adaptix Limited	Pausch Medical GmbH	N/A
Registered Establishment Number	TBD	9610903	N/A
Premarket Submission Number:	K252133	K221949	N/A
Intended use / Indications for use			
	The Adaptix Ortho350 device is intended to be used in hospitals, clinics, imaging centers, and/or other healthcare facilities by qualified/ trained doctors or technicians on both adult and pediatric subjects. The Device is intended to generate tomosynthesis images of human anatomy for diagnostic purposes of body extremities, upper/lower limbs, and adjacent anatomy in all routine radiography examinations. The device is not intended/indicated for use in imaging of the skull, chest, spinal column, hip, shoulder or in mammography applications.	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, with no new issues of safety or effectiveness. The **Adaptix Ortho350** device covers all the body parts explicitly stated in the Intended Use of the predicate device (finger, metacarpus, wrist, foot, ankle, elbow). In addition, the larger detector of the **Adaptix Ortho350** device allows thicker parts of body extremities (e.g. knees) to also be imaged. Both devices are intended to be used in healthcare settings like hospitals, clinics, and imaging centers by qualified healthcare professionals. Their primary purpose is to provide physicians with visualized information to aid in the diagnosis and assessment of orthopedic conditions such as fractures, arthritis, and other bone-related issues.
Device Components			

Workstation	Yes	Yes	Same
System Status Lights	Yes	Yes	Same
Flat panel x-ray detector	Yes	Yes	Same
Detector Specifications			
Digital Flat Panel Detector/Image Receptor	Flat Panel Detector	Flat Panel Detector	Same
Detector Size	16 cm x 24 cm	15 cm x 12 cm	Similar, with no new issues of safety or effectiveness. (**Adaptix Ortho350** has a larger detector size, which means a larger area can be covered in a single exposure.)
Pixel Spacing	98 µm	99 µm	Similar, with no new issues of safety or effectiveness (Both devices have very similar pixel spacing)
Frame Rate	• 45 fps (1×1 binning, Full area) • 90 fps (2×2 binning, Full area) • 500 fps (1×1 binning, 6mm-width area) * Frame Rate (Max.) depends on the ROI size	• Up to 34fps at full resolution, • 86fps in 2x2 pixel binning mode • 300fps in Panoramic Mode Frame Rate (Max.) depends on the ROI size	Similar, with no new issues of safety or effectiveness (The frame rates are **similar**. Both sets offer similar options for binning modes and resolution, but the highest frame rates (500 fps vs. 300 fps) are different, with the first set offering more flexibility in areas like binning and ROI))
ROI Mode	Free ROI	Free ROI	Same
Color Resolution	Mono only	Mono only	Same
Number of pixels	2,430 (w) x 1628 (h) pixels	1488 (w) x 1148 (h) pixels	Similar, with no new issues of safety or effectiveness. (**Adaptix Ortho350** has more pixels, which means a larger area can be covered in a single exposure)
Communication	Gigabit Ethernet	Gigabit Ethernet	Same
A/D Conversion	16 bit	14 bit	Similar, with no new issues of safety or effectiveness (**Adaptix Ortho350** offers a higher bit depth in A/D conversion, which would result in more detailed image data)
Panel Interface	Wired (Ethernet)	Wired (Ethernet)	Same
Spatial resolution	>= 3.4 lp/mm	>= 2.8 lp/mm	Similar, with no new issues of safety or effectiveness

			(**Adaptix Ortho350** offers a higher spatial resolution)
Contrast resolution	at least 10 (out of 17) copper steps can be seen in the images obtained of a Pehamed Fluorad 150 phantom	at least 10 (out of 17) copper steps can be seen in the images obtained of a Pehamed Fluorad 150 phantom	Same
X-ray Source			
kV Range	70 kV (fixed) from a monoblock source emitting X-rays from a square array of positions	60 kV (fixed) from a flat panel X-ray source emitting X-rays from a square array of positions	Similar, with no new issues of safety or effectiveness (**Adaptix Ortho350** operates at slightly higher kV than **Adaptix 3D Ortho Imaging System**). The exact kV is less important for tomosynthesis imaging than it is for 2D X-ray. However, 70 kV makes penetrating thicker tissue easier.
Collimator	Fixed Aperture at fixed SID of 35 cm	Fixed Aperture at fixed SID of 20 cm	Similar, with no new issues of safety or effectiveness (**Adaptix Ortho350** operates at larger SID than **Adaptix 3D Ortho Imaging System**) to cover the wider range of extremities in the intended use (to include knees).
Image Documentation			
DICOM 3 Compliant	DICOM 3.0 File Output	DICOM 3.0 File Output	Same
Workstation			
Wireless Communication (Wi-Fi)/(WLAN)	Both Wi-Fi and WLAN capable	Both Wi-Fi and WLAN capable	Same
USB Ports	Yes	Yes	Same
Printer option	Yes	Yes	Same
Display	1920 x 1080 pixels as standard (all-in-one pc)	1920 x 1080 pixels as standard (laptop)	Same
Pediatric Features			
Pediatric Dose Reduction (IDR)	Software controlled protocols	Software controlled protocols	Same
Adult Dose Reduction (IDR)	Software controlled protocols	Software controlled protocols	Same
Software			
Software Architecture	Adaptix Software Package	Adaptix Software Package (Acquisition & Control)	Similar, with no new issues of safety or effectiveness

	(Acquisition & Control)		(the **Adaptix Ortho350** has additional and upgraded features)
Reconstruction Algorithm	Meshless filtered back projection	Meshless filtered back projection	Same
Graphical User Interface (GUI)	Embedded owner control computer	Embedded owner control computer	Same
Operating system	Windows 11 and above	Windows 10 and above	Similar, with no new issues of safety or effectiveness (using currently supported OS release)
Image manipulation functions	Slice scrolling, zoom, windows level, markers	Slice scrolling, zoom, windows level, markers	Same
Measurement	ruler	ruler	Same
Physical Dimensions			
Height	61 cm 24 in	50 cm 20 in	Similar, with no new issues of safety or effectiveness
Footprint	40 (w) cm x 42(l) cm [15.7 in(w) x 16.5 in (w)	50 (w) cm x 47 (l) cm [20 in(w) x 18.5 in (w)	Similar, with no new issues of safety or effectiveness (the **Adaptix Ortho350** has a base plate rather than a stand)
Weight C-arm	23.6 kg [52 lbs]	15.0 kg [33 lbs]	Similar, with no new issues of safety or effectiveness (**Adaptix Ortho350** is heavier than **Adaptix 3D Ortho Imaging System** by design. This difference has no impact on the intended use or safety of the product.)
Weight Computer	7.8 kg [17.2 lbs] (all-in-one pc)	2.7 kg [6 lbs] (laptop)	Similar, with no new issues of safety or effectiveness (**Adaptix Ortho350** has a heavier computer than **Adaptix 3D Ortho Imaging System** by design. This difference has no impact on the intended use or safety of the product.)
Operating Conditions			
Conditions of Use	Temperature: +10°C to 35°C (50°F to 95° F) Humidity: 30% to 70 % Air Pressure: 79 to 106 kPa	Temperature: +10°C to 40°C (50°F to 104° F) Humidity: 20% to 80 % Air Pressure: 57 to 106 kPa	Similar, with no new issues of safety or effectiveness (Meeting requirements of typical Healthcare facility environment)
Conditions for storage / transportation	Temperature: -10°C to 55°C (14°F to 131° F) Humidity: 30% to 70	Temperature: -10°C to 55°C (14°F to 131° F) Humidity: 20% to 80 % Air Pressure: 57 to 106 kPa	Similar, with no new issues of safety or effectiveness (Meeting requirements of typical transport

	% Air Pressure: 57 to 106 kPa		conditions. No specialized equipment required to control humidity for transport or storage).
Power System			
Input Power	AC: 100-230 V, 50-60 Hz	AC: 100-230 V, 50-60 Hz	Same
EMI Filter	IEC 60601-1-1 and 60601-1-2 compliant	IEC 60601-1-1 and 60601-1-2 compliant	Same
AC Power Cord	Hospital Grade NEMA 5-15	Hospital Grade NEMA 5-15	Same
Isolation Transformer	EN 60601-1, EN 60601-1-1, EN 60601-1-2, EN 61558-1, EN 61558-2-4, UL 60601-1, CAN / CSA 22.2 No. 601.1 / NRTL approval	EN 60601-1, EN 60601-1-1, EN 60601-1-2, EN 61558-1, EN 61558-2-4, UL 60601-1, CAN / CSA 22.2 No. 601.1 / NRTL approval	Similar, with no new issues of safety or effectiveness. The **Adaptix 3D Ortho Imaging System** had transformers located in its control box. **Adaptix Ortho350** has transformers located in the C-arm and also a separate isolation transformer.
Protection type and level against electric shock	Class 1	Class 1	Same
Electrical Safety, Electromagnetic Compatibility standards			
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-28 IEC 60601-2-54	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-28 IEC 60601-2-54	Same

Substantial Equivalence Summary

Based on the information provided above, the Adaptix Ortho350 system shares the same or similar intended use, modes of operation, design and overall technical and functional capabilities, and therefore is substantially equivalent to the selected predicate device Adaptix 3D Orthopedic Imaging System**.**

VII. Performance Testing Summary

The following performance testing was carried out on the Adaptix Ortho350 device:

Biocompatibility Testing

A Biological Evaluation was performed on the Ortho350 device in accordance with ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” and the FDA’s Guidance for Industry and FDA Staff - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The evaluation concluded that the materials used in the Ortho350 device are biocompatible for its intended use and does not pose any biological safety risks to patients.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Adaptix Ortho350 device, consisting of the C-Arm, Isolation Transformer and the Control PC. The testing determined that the electric safety of the Ortho350 Device is acceptable for its intended use, and that the system complies with the IEC 60601-1, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601 -2-54 and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software Verification and Validation testing was performed on the Ortho350 device, in accordance with IEC 62304:2006 + A1:2015 Medical device software — Software life cycle processes and the FDA's Guidance for Industry and FDA Staff Content of Premarket Submissions for Device Software Functions (2023). Overall, the software for the Ortho350 system was determined as a Safety Class 'B' under IEC 62304. All design requirements and risk mitigations passed their planned verification and validation tests.

Cybersecurity Testing

Security Requirements Testing, Threat Mitigation Testing, Vulnerability Testing, and Penetration Testing were performed on the Adaptix Ortho350 System in line with IEC 81001-5-1 (2022) and the FDA's Guidance for Industry and FDA Staff - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023). The testing concluded that the Ortho350 system is safe to install and operate within a HDO environment from a cybersecurity perspective.

Transport Testing

Transport verification was performed on the Ortho350 device within its packaging to ensure that the device could be reliably delivered to end users without sustaining damage that could affect its performance, safety, or usability. The verification was done in accordance with ASTM D4169-22, which included environmental conditioning, mechanical handling (e.g., incline impacts and drops), and vibration testing. The overall testing concluded that the Ortho350 system, along with its chosen packaging solution, can safely endure the rigors of transportation. The overall outcome of the study was a conclusive pass, validating that the product is fit for shipment and capable of immediate operation upon delivery.

Image Verification Testing

Image Quality verification testing was conducted using geometrical phantoms, adult human cadavers and an anthropomorphic pediatric phantom. Digital tomosynthesis images and standard 2D radiographs evaluated by qualified independent radiologists and orthopedic clinicians from the USA and UK. The tests included assessments of the impact of typical image and motion artifacts, including an assessment of image artifacts in the presence of metal. The tests confirmed that images were clinically acceptable and within the intended use for diagnosis for both adult and pediatric patients.

Hardware Verification Testing

Verification of the main hardware components of the Ortho350 device (Source and Stage Control Board and C-Arm Desktop Assembly) were performed against their corresponding requirements. The overall verification activities passed accordingly.

Usability Testing

Usability Engineering in accordance with IEC 62366 Part 1: Application of usability engineering to medical devices and the FDA's Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices was applied throughout the product development process of the Ortho350 system. During development, several rounds of formative evaluations were conducted, with a final summative evaluation documented in the subsequent report confirmed adequate tomosynthesis workflow for orthopedic settings.

VIII. CONCLUSIONS

The subject device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use and the subject device does not raise any new potential safety risks. The conclusions drawn from the nonclinical tests discussed above demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed device K221949.