Orthoscan, Inc.
% Mr. Steve D. Seeman
Director of Quality Assurance and Regulatory Affairs
14555 N. 82nd St.
SCOTTSDALE AZ 85260

June 21, 2019

Re: K183220
Trade/Device Name: OrthoScan TAU 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 and MQB
Dated: June 3, 2019
Received: June 4, 2019

Dear Mr. 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 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,

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)*
K183220

Device Name
OrthoScan TAU Mini C-Arm

Indications for Use *(Describe)*

The OrthoScan TAU Mini C-arm 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.

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ORTHOSCAN
IMAGING EXCELLENCE

510(k) Summary

510 (k) Premarket Notification Submission- OrthoScan TAU Mini C-Arm

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

Submitter Address:	OrthoScan 14555 N 82nd St. Scottsdale, AZ 85260 Phone: (480) 503-8010 Fax: (480) 503-8011
Primary Contact Person:	Richard Westrich 14555 N 82nd St. Scottsdale, AZ 85260 Cell: (909) 262-9930 Phone: (480) 503-8010 Fax: (480) 503-8011
Secondary Contact Person:	Steve Seeman 14555 N 82nd St. Scottsdale, AZ 85260 Phone: (480) 503-8010 Fax: (480) 503-8011

Proposed Device:	**21CFR 807.92(a)(2)**
Device Trade Name:	OrthoScan TAU Mini C-Arm
510(k) Number:	K183220
Common Names:	Fluoroscopic X-Ray System, Mobile Mini Mobile C-arm, Mini C-arm
Device Class:	Class II
Regulation Number:	21CFR 892.1650
Regulation Name:	image-intensified fluoroscopic x-ray system
Product Code:	OXO, JAA, MQB

Primary Predicate Device:	**21 CFR 807.92(a)(3)**
Device Identification:	OrthoScan FD Mini C-Arm (K133174)
Regulation Number:	21CFR 892.1650
Device Class:	Class II
Regulation Name:	Image-intensified fluoroscopic x-ray system
Product Codes:	OXO, JAA, MQB

Secondary Predicate Device:	**21 CFR 807.92(a)(3)**
Device Identification:	Ziehm Solo FD (K161976)
Regulation Number:	21CFR 892.1650
Device Class:	Class II
Regulation Name:	Image-intensified fluoroscopic x-ray system
Product Codes:	OXO, JAA, MQB

General Description:

The OrthoScan TAU Mini C-Arm is 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, knees, and Hips. The system consists of C-arm support attached to the image workstation. The proposed device provides the option of three CMOS flat panel detector sizes and identical X-ray source HVPS monoblock generator assembly with continuous or pulsed operation for image acquisition.

The C-arm supports the CMOS FPD, X-Ray controls, collimator, high voltage generator with a fixed SID imaging. The C-arm and support arm which is connected to the mobile workstation platform are mechanically balanced allowing the operator precise positioning and locking of the vertical, horizontal, orbital and

rotational movements at various angles and distances when imaging the patient's anatomical structures.

The main workstation platform that supports the C-arm assembly contains the power control system, image processing system, system software, monitor display control and main user interface controls. The combination of C-Arm and workstation provides the clinician with a stable platform to obtain precise angles for localizing the patient's anatomical structures and visualization of pathology during live fluoroscopic imaging.

The touch screen interface and keyboard provide user concise selectable imaging, X-ray technique control, entry of patient demographics and related procedural information. The workstation supports both an optional wired or wireless fluoroscopic footswitch allowing optimal positioning for the clinician. The optional connector interface panel of the OrthoScan TAU Mini C-Arm provides convenient connection of peripheral devices such as thermal video printers, image storage devices (USB) and DICOM fixed wire and wireless network interfaces.

Intended Use:

OrthoScan TAU Mini C-Arm is intended to provide fluoroscopic images of the patient including but not limited to, diagnostic, surgical, and critical emergency care procedures during diagnostic or therapeutic treatment/surgical procedures of the upper and lower extremities.

Indications for Use:

The OrthoScan TAU Mini C-Arm 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.

Technology:

The proposed modified device OrthoScan TAU Mini C-arm employs the same fundamental control, and scientific technology as that of our predicate devices OrthoScan FD Mini C-arm (K133174) and the Ziehm Solo FD (K161976).

The radiation control, HVPS X-Ray monoblock generator, power supplies as well as our advanced imaging system are identical to the predicate OrthoScan FD Mini C-arm (K133174).

Software architecture design is identical to that of the predicate device OrthoScan FD Mini C-arm (K133174) with modification of the software to support pediatric indication of use, low dose functionality, processing applications related to the optional range of FPD sizes, Variable beam limiting device, and device specific features.

The primary modifications of the C-Arm include a larger but virtually the same medical grade CsI(T1)/CMOS solid state X-ray detector as that of the predicate OrthoScan FD Mini C-Arm (K133174) and the Ziehm Solo FD (K161976). A variable beam limiting device for precise collimating to anatomical structures, new pre-filter for pediatric imaging, touch control monitor, optional UPS power supply, 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 smaller profile of our predicate OrthoScan FD Mini C-arm (K133174).

Summary of Technological Characteristics:

The following table provides a comparison of the technological characteristics of the proposed device OrthoScan TAU Mini C-Arm to that of the predicate device demonstrates that the scientific and technology characteristics are substantial equivalence to the predicate device OrthoScan FD mini C-Arm (K133174).

Differences Features/Technology:	New Device OrthoScan TAU Mini C-Arm TAU 1512 -1000-0015, TAU 1515- 1000-0016, TAU 2020- 1000-0017	Predicate Device OrthoScan FD 1000-0004 (K133174)	Comparison to Predicate, Comments to Differences
Product Codes			
Device Classification Name	image-intensified fluoroscopic x-ray system, mobile	image-intensified fluoroscopic x-ray system, mobile	Identical
Regulation Description	Image-intensified fluoroscopic x-ray system.	Image-intensified fluoroscopic x-ray system.	Identical

Classification Product Code	OXO	OXO	Identical
Subsequent Product Code	JAA	JAA	Identical
Regulation Number	892.165	892.165	Identical
Device Class	II	II	Identical
Non-Contact Device	Non-Contact	Non-Contact	Identical
510(k) Panel Review	Radiology	Radiology	Identical
510(K) Number	OrthoScan TAU unknown at this time	K133174	OrthoScan TAU unknown at this time
Detector Specifications			
CMOS Flat Panel Detector/Image Receptor	medical grade CsI(T1)/CMOS solid state X-ray detector	medical grade GadOx (T1)/CMOS solid state X-ray detector	All Detectors of the TAU Mini C-Arm are of similar design Technology and Scientific principal to that of the Predicate (K133174) They share the advantages of SSXI image receptors.
Detector Resolution	TAU 2020 = 2.0k x 2.2 k	1.5 k x 1.5 k	Substantially Equivalent. The proposed device has added the ability of a larger FOV for Physician. These changes do not raise new safety or effectiveness concerns.
	TAU 1515 = 1.5 k x 1.5 k		
	TAU 1512 = 2.0 k x 1.5 k		
Field of View (Full)	TAU 2020 = 8" x 8"	5.5" x 5.5"	Substantially Equivalent. The proposed device has added the ability of a larger FOV for Physician. These changes do not raise new safety or effectiveness concerns.
	TAU 1515 = 5.5" x 5.5"		
	TAU 1512 = 5.5" x 4.3"		
Field of View (Collimated Mag Mode)	TAU 2020 = 4" x 4"	4.3" x 4.3"	Substantially Equivalent. The proposed device has added the ability of a larger Field of view for the Physician. These changes do not raise new safety or effectiveness concerns.
	TAU 1515 = 4.3" x 4.3"		
	TAU 1512 = 4.3" x 3.3"		
Detector Size	TAU 2020 = 20 x 20 cm	15.0 x 15.0 (cm)	Substantially Equivalent. The proposed device has added the ability of a larger Field of view for the Physician. The difference does not affect the safety or efficacy of the device.
	TAU 1515 = 15 x 15 cm		
	TAU 1512 = 15 x 12 cm		
Useful Array	TAU 2020 = 20 x 20 cm	15.0 x 15.0 (cm)	Substantially Equivalent.

	TAU 1515 = 15 x 15 cm TAU 1512 = 15 x 12 cm		The proposed device has added the ability of a larger Field of view for the Physician. The difference does not affect the safety or efficacy of the device.
Pixel Spacing	TAU 2020 = 99 microns TAU 1515 = 100 microns TAU 1512 = 75 microns	100 microns	Substantially Equivalent The difference does not affect the safety or efficacy of the device.
Dynamic Range	TAU 2020 = 71 dB TAU 1515 = 71 dB TAU 1512 = 70 dB		Substantially Equivalent The difference does not affect the safety or efficacy of the device.
DQE	TAU 2020 = 70% TAU 1515 = 70% TAU 1512 = 70%		Identical The difference does not affect the safety or efficacy of the device.
Grayscale Resolution	16 bit (65,536 shades of gray)	16 bit (65,536 shades of gray)	Identical
Image Processing Features			
Startup time	30 sec	30 sec	Identical
Cine Loop Export	Yes	Yes	Identical
Fluoroscopy Frame Rate	30/15/7.5/2 fps	30/15/7.5/2 fps	Identical
Edge Enhancement	Yes	Yes	Identical
Post Process Brightness/Contrast	Yes	Yes	Identical
Adaptive Noise Suppression	Automatic	Automatic	Identical
Manual Noise Suppression	3 Modes	3 Modes	Identical
AERC Automatic X-Ray Technique Control	YES	YES	Identical
Adaptive Noise Filter	Nosie reduction	Nosie reduction	Identical
Save and Auto Store	YES	YES	Identical
Last image hold	YES	YES	Identical
Edge Enhancement	YES	YES	Identical
Cine Loop Frame Rate	30 fps	30 fps	Identical
Snapshot Capabilities	YES	YES	Identical
Post Processing (B/C)	YES	YES	Identical
Image invert	YES	YES	Identical
Image Zoom	YES	YES	Identical
Manual Noise Suppression	4 modes	4 modes	Identical
Image Documentation:			
Wireless Communication (Wi-Fi)/(WLAN)	Capable IEEE 802.11	Capable IEEE 802.11	Identical
DICOM 3 Compliant	Yes	Yes	Identical
MPPS	Capable	Capable	Identical

RDSR	YES	YES	Identical
Image Capacity	26, 000	26, 000	Identical
Video Capacity	14.4 min	14.4 min	Identical
Cine Loop Export	Yes	Yes	Identical
TP Link High Gain Wireless USB	Option	Option	Identical
USB Ports	2	2	Identical
Printer option	2	2	Identical
Dose Measurement			
Air Kerma (US-Standard)	YES	YES	Identical
DAP (Optional in the US)	Optional	Optional	Identical
Pediatric Features			
Pediatric Dose Reduction IDR	YES	NO	IDR unique set of features and functions. Pediatric Dose reduction and special features for pediatric population. Dose assessment and image comparison of dose reduction for pediatric confirmed similar image quality with new IDR filter The difference does not affect the safety or efficacy of the device. See Substantially Equivalent
Adult Dose Reduction IDR	YES	NO	IDR unique set of features and functions for Adult population. Dose assessment and image comparison of dose reduction confirmed similar image quality with new IDR filter The difference does not affect the safety or efficacy of the device. Substantially Equivalent
Software			

Software Architecture	OrthoMini Application	OrthoMini Application	Software architecture design is Substantially Equivalent to that of the predicate device OrthoScan FD Mini C-arm (K133174) with modification of the software to support pediatric indication of use, low dose functionality, processing applications related to the optional range of FPD sizes, Variable beam limiting device, and device specific features.
Graphical User Interface (GUI)	OrthoMini Application	OrthoMini Application	Similar operation however, with new device TAU the software is configured to support pediatric functionality not available be on OrthoScan FD. The difference does not affect the safety or efficacy of the device. Substantially Equivalent
Operating system	Windows 8.1 Embedded	Windows 8.1 Embedded	Identical
Pediatric Workflow Support	Yes	No	Not available on predicate The changes to the proposed device do not raise new safety or effectiveness concerns
Measurement	Yes	NO	Not available on predicate The changes to the proposed device do not raise new safety or effectiveness concerns
X-Ray Generator Specifications			
Focal Spot	42.5 microns	42.5 microns	Identical
kV Range	40 – 78 kVp	40 – 78 kVp	Identical
mA Range	0.04 – 0.160 mA	0.04 – 0.160 mA	Identical
Operating Mode	Pulse/ Continuous	Pulse/ Continuous	Identical
Pulse Rate	2 to 30 pps	2 to 30 pps	Identical
Beam Pre-filter 0.1mm Cu	Yes	No	Predicate has 2.5mm AL and complies with the regulations for HVL in x-ray beam. New Device X-ray beam pre-filter helps reduce

			skin entrance dose by adding additional filtration of Cu.
HVL Filter	2.5mm (Al Equivalent)	2.5mm (Al Equivalent)	Identical
Magnification Mode	Yes	Yes	Both support mag modes of operation nearly Identical
Collimator	TAU 1512 Fixed Aperture @ Fixed SID (Normal, Mag)	Fixed Aperture @ Fixed SID (Normal, Mag)	Although not Identical both have similar indented use of collimating X-ray beam providing compliance with the regulations. Substantially Equivalent
	TAU 1515 Fixed Aperture @ Fixed SID (Normal, Mag)		
	TAU 2020 Stepless Collimator with Fixed SID (4 Leaf, 2 Axis)		
Physical Dimensions:			
Source to Image	17.7" (45cm)	17.7" (45cm)	Identical
Free space	13.8"	13.8"	Identical
Arc Depth	20"	19"	Substantially Equivalent Provides more depth for procedures in clinical use. The change to the proposed device does not raise new safety or effectiveness concerns
Pivot	430°	430°	Identical
Lateral Rotation B + Y axis (Wig-Wag)	320°	320°	Identical
Orbital Rotation	160°	150°	Substantially Equivalent The change to the proposed device does not raise new safety or effectiveness concerns
Vertical Range	26.5"	26.5"	Identical
Distance to Cabinet	max 68"	max 68"	Identical
Distance to Wheel base	max 45"	max 45"	Identical
Weight	475lb	400lb	Substantially Equivalent The change to the proposed device does not raise new safety or effectiveness concerns
Height	48"	44.5"	Substantially Equivalent The change to the proposed device does not raise new safety or effectiveness concerns

Footprint	28" x 33"	28" x 33"	Identical
Power System			
Input Power	90-253 VAC @ 47-63 Hz	90-253 VAC @ 47-63 Hz	Identical
EMI Filter	FN2060B-6-06	FN2060B-6-06	Identical
AC Power Cord	Retractable (25ft)	Retractable (25ft)	Identical
Isolation Transformer	Yes	Yes	Identical
EMI Filter	Yes	Yes	Identical
UPS (Battery Backup)	TAU 2020 Optional TAU 1515 Optional TAU 1512 Optional	No	Power system of the Predicate device and the new Device TAU are Substantially Equivalent The proposed new device TAU Mini C-arm added an optional backup battery (UPS) to protect the data integrity of the system if the device experiences a sudden loss of power e.g. power Line outage, accidental disconnect of power cord from main power etc. The UPS allows for limited additional power for controllable exit or to complete a short duration of in-progress procedure. Safety testing confirms this change did not raise any new safety and effectiveness concerns.
Laser Alignment:			
Laser position indicator	Yes	Yes	Identical
Surgical Lights:			
Light bar assemblies	Yes	Yes	Identical

Conclusion:

The changes and differences of the proposed OrthoScan TAU Mini C-Arm described in the table do not change the control mechanism, operating principle, energy type, or intended

use found on predicate device OrthoScan FD Mini C-Arm (K133174). In addition, given the high similarity between the legally marketed Solo FD K161976 and the OrthoScan TAU mini C-Arm K183220 we believe that this additional predicate demonstrates that the OrthoScan TAU mini C-Arm K183220 is intended for the same pediatric populations and provide the same intended use and indication for use when imaging all pediatric patient populations

Adverse Effects on Health:	The proposed OrthoScan TAU 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 OrthoScan 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.
Applicable Standards:	MDD 93/42/EEC Annex II of the European Medical Devices Directive (MDD) 93/42/EEC. EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes IEC 60601-1 Medical Electrical Equipment, General Requirements for Safety Edition 3.0 (+Corr.1+Corr.2), Date: 2005-12-15 IEC 60601-1-2
Applicable Standards:	Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility Edition 3.0, Date: 2007-03-30, Conformance Standard #19-1 IEC 60601-1-3 Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment Edition 2.1, Date: 2013-04 Conformance Standard #12-269

	60601-2-28 Edition 2 (2010/03/10) Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis Conformance Standard #12-309
Applicable Standards:	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 1.0, Date: 2009-06-29 Conformance Standard #12-274 IEC 60825-1 Safety of laser products, Equipment Safety, requirements, and user guide Edition 2.0, Date: 2007-03-30 Conformance Standard #12-273 ISO 14971 Medical devices - Application of risk management to medical devices Edition 2.0, Date: 2007-03-01 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 6060-1-1 ED 3 series, including IEC 60601-2-54. Further device met all applicable sections of 21 CFR Subchapter J performance standards. The OrthoScan TAU 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 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. 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, images were taken by both the new TAU Mini C-arm and predicate device OrthoScan FD (K133174) and the Ziehm Solo FD (K161976). Image comparison sets taken were representative of both the adult and pediatric populations. A Radiologist performed an assessment of 330 individual images arranged in 20 groups of image sets. His conclusion was the image quality combined with a reduced patient dosage will result in a significant improvement in patient care for the TAU device over the Predicate device. Therefore, OrthoScan believes the TAU Mini C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate devices at a lower entrance dose level.

Summary of Clinical Test Data:

OrthoScan TAU mobile fluoroscopic mini 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, OrthoScan 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 OrthoScan TAU Mini C-Arm in comparison to the predicate OrthoScan FD Mini C-Arm K133174. Evaluation of the 330 individual images arranged in 20 groups of 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 significant improvement in patient care for the TAU device. 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.