October 21, 2021

Orthoscan, Inc.
℅ Mr. Kevin Bridgman
Director of Regulatory Affairs and Quality Assurance
14555 N. 82nd Street
SCOTTSDALE AZ 85260

Re: K213113
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, MQB
Dated: September 21, 2021
Received: September 27, 2021

Dear Mr. Bridgman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213113

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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K213113

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

Volume 005 Special 510(k) Summary

Special 510 (k) Premarket Notification Submission- Orthoscan, Inc. TAU Mini C-Arm

Date: September 21, 2021

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

Submitter Address:	Orthoscan, Inc. 14555 N 82nd St. Scottsdale, AZ 85260 Phone: (480) 503-8010 Fax: (480) 503-8011
Primary Contact Person:	Kevin Bridgman 14555 N 82nd St. Scottsdale, AZ 85260 Cell: (909) 262-9930 Phone: (480) 503-8010 Fax: (480) 503-8011
Secondary Contact Person:	Brenda Sparks 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, Inc. TAU Mini C-Arm
510(k) Number:	Unknown at this time
Common /Usual Names:	Fluoroscopic X-Ray System, Mobile Mini Mobile C-arm, Mini C-arm
Device Class:	Class II
Classification(s):	21CFR 892.1650
Classification Names:	image-intensified fluoroscopic x-ray system, mobile
Device:	Image-intensified fluoroscopic x-ray system.
Product Code:	OXO, JAA, MQB

Predicate Device:	**21 CFR 807.92(a)(3)**
Device Identification:	Orthoscan, Inc. TAU Mini C-Arm (K183220)
Classification(s):	21CFR 892.1650
Device Class:	Class II
Classification Names:	Image-intensified fluoroscopic x-ray system, mobile
Regulation Description:	Image-intensified fluoroscopic x-ray system
Product Codes:	OXO, JAA, MQB

General Description:

The proposed modifications to Orthoscan, Inc. TAU Mini C-Arm series (which we will refer to internally and in this submittal as Orthoscan TAU 2.0, for distinction from predicate Orthoscan TAU) retain identical function as the predicate TAU Mini C-arm (K183220) as a mobile fluoroscopic mini C-arm system that provides fluoroscopic images of patients of all ages during diagnostic, treatment and surgical procedures involving anatomical regions such as but not limited to that of extremities, limbs, shoulders, knees, and Hips. The system consists of C-arm support attached to the image workstation.

The changes to the Orthoscan TAU series of Mini C-arm X-ray systems represent a modification of our presently legally marketed device Orthoscan TAU mini C-Arm K183220. The proposed modifications to the predicate encompass the implementation of an optional IGZO 15 cm x 15 cm Flat Panel Detector (FPD) in the 15x12cm and 15x15cm device detector sizes, a new LINUX based operating system and related software, image processing board revisions and a revised Power Manager Board for AC to DC conversion that will distribute 24Vdc via a medical grade DC power supply. The proposed device incorporates software architecture and other improvements that

replicate the features and functions of the predicate device and improve image clarity without increasing dose levels.

For both the predicate and proposed device, the following are unchanged; Identical C-arm support and mechanical connections, balancing, locking, rotations, work-station platform, monitor display and main user interface controls, touch screen interface, selectable imaging, X-ray technique control, entry of patient information, wired or wireless footswitch operation, interface connection panel and DICOM fixed wire and wireless network interfaces.

Intended Use:

The proposed modifications to Orthoscan, Inc. TAU Mini C-Arm series do not change the identical intended use. Intended use is the same as the predicate device TAU (K183220) Mini C-Arm.

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.

The proposed modifications to Orthoscan, Inc. TAU Mini C-Arm series do not change the indications for use. The indications for use are the same as the predicate device TAU (K183220) Mini C-Arm.

Technology:

The changes to proposed device Orthoscan TAU 2.0 series of Mini C-arm X-ray systems represent a modification of our presently legally marketed device Orthoscan TAU Mini C-Arm K183220. The proposed device will provide an option in supplier of detectors. The optional IGZO Solid-State X-ray Imagers (SSXI) provide newer technology in the Flat Panel Detectors (FPD). The inclusion of IGZO detector size 15cmx15cm in the 15cmx15cm sized Orthoscan device will also be fitted into the smaller active field

model 15cmx12cm sized device with minor mechanical modifications.

The proposed modified TAU 2.0 will be equipped with a revised Power Manager Board for AC to DC conversion that will distribute 24vdc via a new medical grade DC power supply. This supply will power all electronic sub-assemblies. The AC to DC conversion will provide intrinsic value through risk reduction such as leakage, while standardizing distribution of 24Vdc.

With the introduction of a Linux based operating system (OS) an open source highly secure OS, and revisions to the image processing board, software architecture design has been improved and functions are identical to that of the predicate device Orthoscan, Inc. TAU Mini C-arm (K183220).

Summary of Technological Characteristics:

The comparisons of the proposed modifications to Orthoscan, Inc. TAU Mini C-Arm demonstrate that the scientific and technology characteristics indicate substantial equivalence to the predicate device Orthoscan, Inc. TAU Mini C-Arm (K183220). The following table provides a comparison of the technology characteristics.

	Modified Device Orthoscan, Inc. TAU 2.0 Mini C-Arms model#/sizes, serial number prefix: 1000-0015, 15x12cm, Serial No. sequence 5Txxx 1000-0016, 15x15cm, Serial No. sequence 5Uxxx 1000-0017, 20x20cm, Serial No. sequence 5Vxxx	Predicate Device Orthoscan, Inc. TAU Mini C-Arms model#/sizes, and serial number prefix; 1000-0015, 15x12cm, Serial No. sequence 5Nxxx 1000-0016, 15x15cm, Serial No. sequence 5Pxxx 1000-0017, 20x20cm, Serial No. sequence 5Rxxx (K183220)	Comparison to Predicate, Comments to Differences
Differences Features/Technology:			
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	New Proposed Device - unknown at this time	K183220	New Proposed Device - unknown at this time
Detector Specifications			
CMOS and IGZO Flat Panel Detector/Image Receptor	CsI(T1)/ solid state X-ray detector 20x20cm remains CMOS same as predicate. 15x12cm and 15x15cm will be CMOS or optional IGZO	CsI(T1)/ solid state X-ray detector 20x20cm, 15x15cm and 15x12cm are CMOS	Substantially Equivalent. The introduction of the optional IGZO technology was found to be equal in safety and effectiveness including image quality (Essential Performance). IGZO sensor technology demonstrates equal/ better image quality to that of the predicate. The IGZO detector features the same scintillator technology and equal or improved active area, pixel pitch, frame rate, X-Ray energy, power specifications and mechanical dimensions, and also has identical image processing features as the predicate. IGZO based detectors are manufactured using processes that are similar to CMOS detectors. The slight differences in used sensor glass technology does not have influence on safety & effectiveness of the product and provides slightly improved image quality at equal dose values as the predicate.
Detector Resolution	TAU 2.0 2020 =2.0k x 2.2k TAU 2.0 1515 =1.5 k x 1.5k TAU 2.0 1512 =2.0 k x 1.5k	TAU 2020 =2.0k x 2.2 k TAU 1515 =1.5k x 1.5k TAU 1512 =2.0 x 1.5k	Identical

Field of View (Full)	TAU 2.0 2020 = 8" x 8" TAU 2.0 1515 = 5.5" x 5.5" TAU 2.0 1512 = 5.5" x 4.3"	TAU 2020 = 8" x 8" TAU 1515 = 5.5" x 5.5" TAU 1512 = 5.5" x 4.3"	Substantially Equivalent. The 15x12cm model will be mechanically modified to house the 15x15cm IGZO Flat Detector for a useful array area 15x12cm. The difference does not affect the safety or efficacy of the device
Field of View (Collimated Mag Mode)	TAU 2.0 2020 = 4" x 4" TAU 2.0 1515 = 4.3" x 4.3" TAU 2.0 1512 = 4.3" x 3.3"	TAU 2020 = 4" x 4" TAU 1515 = 4.3" x 4.3" TAU 1512 = 4.3" x 3.3"	Identical to predicate
Detector Size	TAU 2.0 2020 = 20 x 20cm TAU 2.0 1515 = 15 x 15cm TAU 2.0 1512 = 15 x 15cm	TAU 2020 = 20 x 20 cm TAU 1515 = 15 x 15 cm TAU 1512 = 15 x 12 cm	Substantially Equivalent. The TAU 2.0 (15x12cm) model will be mechanically modified to house the 15x15cm IGZO Flat Detector for a useful array area 15x12cm. The difference does not affect the safety or efficacy of the device.
Useful Array	TAU 2.0 2020 = 20 x 20cm TAU 2.0 1515 = 15 x 15cm TAU 2.0 1512 = 15 x 15cm	TAU 2020 = 20 x 20 cm TAU 1515 = 15 x 15 cm TAU 1512 = 15 x 12 cm	Substantially Equivalent. The TAU 2.0 (15x12cm) model will be mechanically modified to house the 15x15cm IGZO Flat Detector for a useful array area 15x12cm. The difference does not affect the safety or efficacy of the device.
Pixel Spacing	TAU 2.0 2020 = 99 microns TAU 2.0 1515 = same for CMOS or 100microns for IGZO detector TAU 2.0 1512 = same for CMOS or 100microns for IGZO detector	TAU 2020 = 99 microns TAU 1515 = 100 microns TAU 1512 = 75 microns	Substantially Equivalent. The difference for the TAU 2.0 15x12 cm IGZO detector pixel spacing does not affect the safety or efficacy of the device.
Dynamic Range	TAU 2.0 same for CMOS or >69dB for IGZO	TAU 2020 = 71 dB TAU 1515 = 71 dB TAU 1512 = 70 dB	Substantially Equivalent The difference in dynamic range for the IGZO detector does not affect the safety or efficacy of the device.

DQE	TAU 2.0 2020 = 70% TAU 2.0 1515 = same for CMOS or 65% for IGZO TAU 2.0 1512 = same for CMOS or 65% for IGZO	TAU 2020 = 70% TAU 1515 = 70% TAU 1512 = 70%	Substantially Equivalent. The difference in DQE for the IGZO detector does not affect the safety or efficacy of the device.
A/D Conversion	16 bit	16 bit	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	Noise reduction	Noise 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 Brightness/Contrast Control	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	YES	Identical
Adult Dose Reduction IDR	YES	YES	Identical
Software			
Software Architecture	OrthoTouch Application	OrthoMini Application	Software architecture design is Substantially Equivalent to that of the predicate device Orthoscan, Inc. TAU Mini C-arm (K183220). The OrthoTouch Application provides the main user interface to Orthoscan fluoroscopic X-Ray products, identical to OrthoMini, application. OrthoTouch on LINUX operating system performs equal to OrthoMini.
Graphical User Interface (GUI)	OrthoTouch Application	OrthoMini Application	Substantially Equivalent GUI application are nearly Identical in workflows to achieve the same basic functionality with new proposed device software application. During verification and validation activities this change did not raise any safety and/or effectiveness concerns. The difference does not affect the safety or efficacy of the device.
Operating system	LINUX Ubuntu 16.04, Embedded	Windows 8.1 Embedded	Substantially Equivalent operating system was shown to support nearly identical workflows to achieve the same basic functionality with new proposed device software application. During verification and validation activities this change did not raise any safety and/or effectiveness concerns. The difference does not affect the safety or efficacy of the device.

Pediatric Workflow Support	Yes	Yes	Identical
Measurement	Yes	Yes	Identical
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	Yes	Identical
HVL Filter	2.5mm (Al Equivalent)	2.5mm (Al Equivalent)	Identical
Magnification Mode	Yes	Yes	Identical
Collimator	TAU 1512 Fixed Aperture @ Fixed SID (Normal, Mag)	TAU 1512 Fixed Aperture @ Fixed SID (Normal, Mag) TAU 1515 Fixed Aperture @ Fixed SID (Normal, Mag) TAU 2020 Stepless Collimator with Fixed SID (4 Leaf, 2 Axis)	Identical
	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"	20"	Identical
Pivot	430°	430°	Identical
Lateral Rotation B + Y axis (Wig-Wag)	320°	320°	Identical
Orbital Rotation	160°	160°	Identical
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	475lb	Identical

Height	49"	49"	Identical
Footprint	28" x 33"	28" x 33"	Identical
Power System			
Input Power	250W AC to DC 24 24Vdc, 90-264 VAC @ 50/60Hz power supply medical grade.	90-253 VAC @ 47-63 Hz	Substantially equivalent.
EMI Filter	Yes	FN2060B-6-06	Substantially Equivalent. TAU 2.0 consist of an AC to DC 24vdc power supply with in line filter and isolation.
AC Power Cord	Retractable (25ft)	Retractable (25ft)	Identical
Isolation Transformer	Yes	Yes	Substantially Equivalent. TAU 2.0 consist of an AC to DC 24vdc power supply with in line filter and isolation.
UPS (Battery Backup)	TAU 2020 Optional TAU 1515 Optional TAU 1512 Optional	TAU 2020 Optional TAU 1515 Optional TAU 1512 Optional	Identical
Laser Alignment:			
Laser position indicator	Yes	Yes	Identical
Surgical Lights:			
Light bar assemblies	Yes	Yes	Identical

Conclusion of Table Information:

The changes and differences of the proposed Orthoscan, Inc. TAU Mini C-Arm described in the table do not change the control mechanism, operating principle, energy type, or intended use found on the predicate device Orthoscan, Inc. TAU Mini C-Arm (K183220).

Adverse Effects on Health:	The proposed modified Orthoscan, Inc. 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, Inc. Quality System, and system verification and validation testing ensure the device performs to the product specifications and its intended use. The adherence to these applicable regulations and certification to Recognized Consensus Standards that apply to this product provides the assurance of device safety and effectiveness.
Applicable Standards:	Annex II of the European Medical Devices Directive (MDD) 93/42/EEC. Please see EC Certificate for predicate devices EC Declaration of Conformity in VOL_009_FILES 003 and FILE 009 EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes. Date: 2016. Please see Certificate in Volume 009 File 013 IEC 60601-1 Medical Electrical Equipment, General Requirements for Safety IEC 60601-1:200 5 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint). No Recognized Conformance Standard but is general basis of AAMI/ANSI ES60601-1 conformance standard 19-4. Please see CB test report in VOL_017_EMC-Eectrical Safety _FILE007 IEC 60601-1-2 MEDICAL ELECTRICAL EQUIPMENT – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests IEC 60601-1-2:2014 Conformance Standard #19-8 Please see CB test report in VOL_017_FILE017 and FILE019

IEC 60601-1-3

Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment

Edition 2.1, Date: 2013 Conformance Standard #12-269

Please see CB test report in VOL017_EMC-Eectrical Safety_FILE009

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

Please see CB test report in VOL017_EMC-Electrical Safety FILE011

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, 2015 #12-296

Please see CB test report in VOL017_EMC-Electrical Safety FILE013

Orthoscan understands that the FDA will accept declarations of conformity, in support of premarket submissions, to [Rec # 12-296] until September 28, 2021. After this transition period, declarations of conformity to [Rec # 12-296] will not be accepted.

IEC 60825-1

Safety of laser products, Equipment Safety, requirements, and user guide

Edition 2.0, Date: 2007-03-30 Conformance Standard #12-273

See predicate (k183220) Test reports VOL_018_ Performance testing

ISO 14971

Medical devices - Application of risk management to medical devices

Edition 2.0, Date: 2007-03-01 Conformance Standard #5-40

Compliance is shown by risk management and software Verification and Validation documentation see Volume 016_Software.

Determination of Substantial Equivalence:

Summary Bench Testing

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

The device was tested by notified test laboratory resulting in device being certified compliant with 60601-1 ED 3 series, including IEC 60601-2-54. Further, the device met all applicable sections of 21 CFR Subchapter J performance standards.

The proposed modified Orthoscan, Inc. 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. 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 modified and the predicate device Orthoscan, Inc. TAU (K183220). Numerous Image comparison sets were taken and a Radiologist performed an assessment of individual images arranged in groups of image sets. His conclusion was the image quality at same or similar patient dose rates will result in a slight improvement in patient care (images) for the proposed modified TAU device over the Predicate device. Therefore, Orthoscan, Inc. believes the TAU Mini C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Orthoscan, Inc. TAU (k183220).

Summary of Clinical Test Data:	Orthoscan, Inc. TAU mobile fluoroscopic Mini C-arm system did not require live human clinical studies to support substantial equivalence in accordance with the TAU 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, Inc. conducted a lab test image comparison study employing the use of anthropomorphic phantoms in establishing substantial equivalence based on the modifications to the proposed device and the bench data taken with Orthoscan, Inc. TAU Mini C-Arm in comparison to the predicate Orthoscan, Inc. TAU Mini C-Arm (k183220). Evaluation of the images was conducted by a board-certified Radiologist. His conclusion was the image quality at the same or equivalent patient dosage will result in a slight improvement in patient care (images) for the proposed modified TAU device over the Predicate 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.
Conclusion:	Orthoscan, Inc. considers the proposed modified Orthoscan, Inc. TAU Mini C-arm to be as safe, as effective, and performs substantially equivalent to the predicate device Orthoscan, Inc. TAU Mini C-arm (K183220) in accordance with its labeling.