August 19, 2026

Youngeun Lee
% DRTECH Corporation
Assistant Manager
Suite #1, 2 Floor /Suite # 2, 3 Floor, 29
Dunchon-Daero 541 Beon-Gil, Jungwon-Gu
SEONGNAM-SI, GYEONGGI 13216 3216
REPUBLIC OF KOREA

Re: K261413
Trade/Device Name: Extron 3; Extron 6
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: April 10, 2026
Received: July 24, 2026

Dear Youngeun Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

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
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261413

Please provide the device trade name(s).

EXTRON 3;
EXTRON 6

Please provide your Indications for Use below.

EXTRON Series are a mobile fluoroscopic X-ray system with high output capacity, high thermal capacity and high resolution image processing system, which provides X-ray images of the patient's anatomy during surgery or treatment. This device plays an important role in emergency injury treatment, orthopedic surgery, neurosurgery surgery, bone surgery, etc. This device has a function to save important a specific images as records, so you can easily search for the images and transmit it to the PACS system in the hospital to help the medical staff in diagnosis.
Examples of a clinical application may include: Neurosurgery, Orthopedics, Anesthesiology, Urology, Gynecology, Internal Medicine
(※ This device is not intended for mammography applications.)

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

[As required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

August 19, 2026

2. Submitter's Information [21 CFR 807.92(a) (1)]

- Name of Sponsor: DRTECH Corporation
- Address: Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13216, Republic of Korea
- Contact Name: Youngeun Lee
- Telephone No.: + 82-31-779-7705
- Fax No.: + 82-31-779-7790
- Email Address : drtechra@drtech.com
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

- Trade Name: EXTRON 3, EXTRON 6
- Common Name: Mobile Fluoroscopic X-ray System
- Classification Name: Image-intensified fluoroscopic x-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1650
- Product Code: OWB, OXO, JAA
- Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

	Predicate Device	Reference 1	Reference 2
510(k) Number:	K250010	K122234	K142708
Applicant:	DRTECH Corporation	GE HEALTHCARE SURGERY GE OEC MEDICAL SYSTEMS, INC	PHILIPS MEDICAL SYSTEMS NETHRLANDS BV
Trade Name:	EXTRON 3, EXTRON 5, EXTRON 7	OEC 9900 ELITE	VERADIUS UNITY
Classification Name:	Image-intensified fluoroscopic x-ray system		
Classification Panel:	Radiology		
Classification Regulation:	21 CFR 892.1650		
Product Code:	OWB, JAA, OXO		
Device Class:	II		

5. Description of the Device [21 CFR 807.92(a) (4)]

EXTRON Series are mobile fluoroscopic X-ray systems with high output capacity, high thermal capacity, and high-resolution image processing systems that provide X-ray images of the patient's anatomical structures during surgery or treatment. This device plays an important role in emergency injury treatment, orthopedic surgery, neurosurgery surgery, bone surgery, etc. This device has a function to save important a specific images as records, so you can easily search for the images and transmit it to the PACS system in the hospital to help the medical staff in diagnosis.

The EXTRON Series are composed of a C-arm main body and a monitor cart. The C-arm main body is composed of an X-ray tube, a flat panel detector, a collimator, a generator, a touch panel, foot switch, hand switch and an XConsoleOP program, while the monitor cart is composed of a monitor, a thermal transfer printer, a mouse, a keyboard and an XConsole program.

The operating principle of the device is designed to expose the patient to X-ray beams. The range of X-ray irradiation are adjusted by the collimator.
X-rays can penetrate into the human body through a two-step conversion process.
X-ray photons are converted into light. The light is then converted into electrical signals through the sensor. The electrical charges are transmitted as the sensor output and converted into signals. These signals are digitized and captured by memory. The captured images are processed and displayed on the monitor. The displayed images can be saved or transmitted to an external storage device, such as a network printer.

6. Indications for Use [21 CFR 807.92(a)(5)]

EXTRON Series are a mobile fluoroscopic X-ray system with high output capacity, high thermal capacity and high resolution image processing system, which provides X-ray images of the patient's anatomy during surgery or treatment. This device plays an important role in emergency injury treatment, orthopedic surgery, neurosurgery surgery, bone surgery, etc. This device has a function to save important a specific images as records, so you can easily search for the images and transmit it to the PACS system in the hospital to help the medical staff in diagnosis.
Examples of a clinical application may include: Neurosurgery, Orthopedics, Anesthesiology, Urology, Gynecology, Internal Medicine

(※ This device is not intended for mammography applications.)

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device [21 CFR 807.92(a)(6), 21 CFR 807.92(b)]

The EXTRON Series are designed as a combination of components, including a C-arm, X-ray tube and housing, flat panel detector, digital imaging system, collimator, generator, and monitor cart. Its purpose is to provide X-ray images of a patient's anatomy during surgery or treatment.

The subject device has the same fundamental scientific technologies as the predicate devices. The technological comparison table below demonstrates the comparability of the technological characteristics of the new device and the currently cleared predicate devices. The Technological differences do not affect the intended use of the device.

The table 1 below compares the main performance data of the subject device with the predicate devices to substantiate equivalence of the subject device and predicates.

Table 1. Comparison of the Subject Device (EXTRON 3/6) with Predicate and Reference Devices

Parameter	Subject Device	Predicate Device	Reference 1	Reference 2	Discussion
510(K) Number	K261413	K250010	K122234	K142708	-
Manufacturer	DRTECH Corporation	DRTECH Corporation	GE HEALTHCARE SURGERY GE OEC MEDICAL SYSTEMS, INC	Philips Medical Systems Nederland B.V.	-
Model Name	EXTRON 3, EXTRON 6	EXTRON 3, EXTRON 5, EXTRON 7	OEC 9900 ELITE	Veradius Unity	-
Classification Name	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Equivalent
Classification Panel	Radiology				Radiology
Classification Regulation	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	Equivalent
Product Code	OWB, OXO, JAA	OWB, OXO, JAA	OWB, JAA, OXO	OWB, OXO, JAA	Equivalent
Device Class	Class II	Class II	Class II	Class II	Equivalent
Indications for Use	EXTRON Series are a mobile fluoroscopic X-ray system with high output capacity, high thermal capacity and high resolution image processing system, which provides X-ray images of the patient's anatomy during surgery or	EXTRON Series are a mobile fluoroscopic X-ray system with high output capacity, high thermal capacity and high resolution image processing system, which provides X-ray images of the patient's anatomy during surgery or	The OEC® 9900 Elite Mobile Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of	The proposed Veradius Unity device is intended to be used and operated by: adequately trained, qualified, and authorized health care professionals such as physicians, surgeons, cardiologists, radiologists, and	Equivalent

Parameter	Subject Device	Predicate Device	Reference 1	Reference 2	Discussion
	treatment. This device plays an important role in emergency injury treatment, orthopedic surgery, neurosurgery surgery, bone surgery, etc. This device has a function to save important a specific images as records, so you can easily search for the images and transmit it to the PACS system in the hospital to help the medical staff in diagnosis. Examples of a clinical application may include: Neurosurgery, Orthopedics, Anesthesiology, Urology, Gynecology, Internal Medicine (※ This device is not intended for mammography applications.)	treatment. This device plays an important role in emergency injury treatment, orthopedic surgery, neurosurgery surgery, bone surgery, etc. This device has a function to save important a specific images as records, so you can easily search for the images and transmit it to the PACS system in the hospital to help the medical staff in diagnosis. Examples of a clinical application may include: Neurosurgery, Orthopedics, Anesthesiology, Urology, Gynecology, Internal Medicine (※ This device is not intended for mammography applications.)	clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.	radiographers, who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional, and surgical procedures on all patients except neonates (birth to one month), within the limits of the device. The device is to be used in healthcare facilities both inside and outside the operating room, in sterile as well as non-sterile environments, in a variety of procedures. Applications • Orthopedic • Neuro • Abdominal • Vascular • Thoracic • Cardiac	
Target population	Patients who need X-ray radiography or fluoroscopy images Adults and Pediatrics	Patients who need X-ray radiography or fluoroscopy images Adults and Pediatrics	Patients who need fluoroscopic and spot-film images	Patients who need diagnostic, interventional and surgical procedures, except neonates (birth to one month)	Equivalent
Mobile Platform	Yes	Yes	Yes	Yes	Equivalent

Parameter	Subject Device	Predicate Device	Reference 1	Reference 2	Discussion
X-ray tube	EXTRON 3 : Stationary Anode EXTRON 6: Rotating Anode	EXTRON 3 : Stationary Anode EXTRON 5 : Rotating Anode EXTRON 7: Rotating Anode	Rotating Anode	Rotating Anode	Equivalent
X-ray Generator Manufacturer / Model	EXTRON 3 : Powersite / MB-C5B EXTRON 6 : IMD / HF1 R/8	EXTRON 3 : Powersite / MB-C5B EXTRON 5, EXTRON 7 : IMD / HF1 R/8	-	-	Equivalent
X-ray Tube Manufacturer / Model	EXTRON 3 : RADII / KL188-0.6/1.2-125 EXTRON 6 : IAE / RTM 780 H	EXTRON 3 : EXTRON 3 : RADII / KL188-0.6/1.2-125 EXTRON 5, EXTRON 7 : IAE / RTM 780 H	-	-	Equivalent
Radiographic Mode	[Optional] kV Range : 40 to 120kV mA Range EXTRON 3 - Up to 100mA EXTRON 6 - Up to 100mA	kV Range : 40 to 120kV mA Range EXTRON 7 - Up to 150mA EXTRON 5 - N/A EXTRON 3 - Up to 100mA	kV Range : 40 to 120kV mA Range : Up to 150mA	kV Range : 40 to 120kV mA Range : Up to 125mA	Equivalent
Fluoroscopic Mode	kV Range : 40 to 120kV mA Range : EXTRON 3 - Up to 30mA EXTRON 6 - Up to 60mA	kV Range : 40 to 120kV mA Range : EXTRON 3 - Up to 30mA EXTRON 5 - Up to 40mA EXTRON 7 - Up to 60mA	kV Range : 40 to 120kV mA Range : - Normal : 0.2- 10 mA - High Level Fluoro : 1.0 - 40 mA	kV Range : 40 to 120kV mA Range : 1 to 60mA	Equivalent

Dimension		Immersion Depth EXTRON 3 - 73cm EXTRON 6 - 74cm Free Space : 80cm Orbital movement EXTRON 3 - 165°, 180° EXTRON 6 - 165°, 180°	Immersion Depth EXTRON 3 - 73cm EXTRON 5 - 74cm EXTRON 7 - 74cm Free Space : 80cm Orbital movement : 165°	Immersion Depth : 84cm Free Space : 79cm Orbital movement : 145°	Immersion Depth : 73cm Free Space : 77cm Orbital movement : 145°	Equivalent : Alteration in the dimension does not give rise to any novel concerns regarding safety and effectiveness. Additionally, due to the greater scope of movement, the Subject device offers a higher degree of convenience compared to the Predicate device.
Laser Guide		Yes	Yes	Yes	Yes	Equivalent
Foot Switch		Wired Foot Switch Wireless Foot Switch	Wired Foot Switch Wireless Foot Switch	Wired Foot Switch Wireless Foot Switch	Wired Foot Switch Wireless Foot Switch	Equivalent
Detector	Pixels	EXPD 2121PB : 1500 x 1500 pixels EXPD 2323PB:1536 x 1536 pixels	EXPD 2121P : 1500 x 1500 pixels EXPD 2323P : 1536 x 1536 pixels	21 cm FPD : 1536 x 1496 pixels 31 cm FPD : 1548 x 1524 pixels	1560 x 1420 pixels	Equivalent

Parameter		Subject Device	Predicate Device	Reference 1	Reference 2	Discussion
		EXPD 3030P : 2048 x 2048 pixels	EXPD 2323PB:1536 x 1536 pixels EXPD 3030P : 2048 x 2048 pixels			
	DQE	55% @1lp/mm	55% @1lp/mm	21 cm FPD : Typical 63% @0.5lp/mm 31 cm FPD : Typical 62% @0.5lp/mm	70% @ 0p/mm	Equivalent
	MTF	55% @1lp/mm	55% @1lp/mm	-	59% @ 1lp/mm	Equivalent

8. Summary of Non-Clinical Data [21 CFR 807.92(b)(1)]

The EXTRON Series comply with the following international and FDA-recognized consensus standards list in Table 2.

Table 2. International and FDA-recognized consensus standards

Standards development organization, reference number, and date	Standard name
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54 Edition 2.0 2022-09	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-43 Edition 3.0 2022-12	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
ANSI UL 2900-1 First Edition 2017	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements

IEC 81001-5-1 Edition 1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

And EXTRON Series comply with the FDA guidance documents listed in Table 3.

Table 3. FDA Guidance Documents

Title of Guidance Document	Issue Date
Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	July 28, 2014
Guidance for Industry and FDA Staff: Content of Premarket Submissions for Device Software Functions	June 14, 2023
Guidance for Industry and Food and Drug Administration Staff: Medical X-Ray Imaging Devices Conformance with IEC Standards	May 8, 2019
Guidance for Industry and FDA Staff: Electromagnetic Compatibility (EMC) of Medical Devices	June 3, 2022
Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices	February 3, 2016
Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	September 27, 2023

Bench testing and related documentation performed in accordance with Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices

Sample clinical images representative of the indicated anatomies and populations have been taken for both the proposed devices (EXTRON 3, EXTRON 6) and the predicate devices (EXTRON 5/7/3(K250010)). These images have been reviewed and compared by qualified clinical experts. As a result of this evaluation, it has been confirmed that the EXTRON Series devices provide equivalent image quality to the predicate devices.

9. Summary of Clinical Data [21 CFR 807.92(b)(2)]

Clinical images were taken and reviewed by qualified clinicians to support SE (see Section 8 for more details).

10. Conclusion [21 CFR 807.92(b)(3)]

The EXTRON Series are substantially equivalent to the currently marketed predicate devices (EXTRON 5/7/3(K250010)) in terms of design, fundamental scientific technology, and indications for use, safety, and effectiveness.
Substantial equivalence for Mobile fluoroscopic X-ray System was demonstrated through the non-clinical performance in compliance with the requirements specified in the international and FDA recognized consensus standards, ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, IEC 60601-2-43, IEC 62304, ANSI UL 2900-1, and IEC 81001-5-1.
The comparison of technological characteristics, non-clinical performance data and safety testing demonstrate that the EXTRON Series are substantially equivalent to the predicate devices.