August 17, 2023

DRTECH Corporation
℅ Kim Minjeong
Manager
Suite No. 1, 2 Floor/Suite No. 2, 3 Floor, 29,
Dunchon-Daero 541 Beon-Gil, Jungwon-Gu
Seongnam-si, Gyeonggi-do 13216
SOUTH KOREA

Re: K230871
Trade/Device Name: Extron 5, Extron 7
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: March 31, 2023
Received: July 21, 2023

Dear Kim Minjeong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230871

Device Name
EXTRON 5, EXTRON 7

Indications for Use *(Describe)*
EXTRON5 and EXTRON 7 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.)

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."

DRTECH

510(k) Summary

K230871

[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)]

03/31/2023

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: Minjeong Kim
- Telephone No.: + 82-31-779-7783
- 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 5, EXTRON 7
- 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)]

- 510(k) Number: K142708
- Applicant: GENERAL ELECTRIC COMPANY
- Trade Name: 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 5 and EXTRON 7 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 5 and EXTRON 7 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. Indication for Use [21 CFR 807.92(a)(5)]

EXTRON5 and EXTRON 7 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 5 and EXTRON 7 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 5, EXTRON 7) to the Predicate Device (Veradius Unity)Substantial Equivalence

Parameter	Subject Device	Predicate Device	Discussion
510(K) Number	**Unknown**	K142708	-
Manufacturer	DRTECH Corporation	Philips Medical Systems Nederland B.V.	-
Model Name	EXTRON 5, EXTRON 7	Veradius Unity	-
Classification Name	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Identical
Classification Panel	Radiology		Identical
Classification Regulation	21 CFR 892.1650	21 CFR 892.1650	Identical
Product Code	OWB, OXO, JAA	OWB, OXO, JAA	Identical
Device Class	Class II	Class II	Identical
Intended Use	EXTRON5 and EXTRON 7 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.	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 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	Identical

	Examples of a clinical application may include: Neurosurgery, Orthopedics, Anesthesiology, Urology, Gynecology, Internal Medicine (※ This device is not intended for mammography applications.)	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 diagnostic, interventional and surgical procedures, except neonates (birth to one month)	Identical
Mobile Platform	Yes	Yes	Identical
Max. Output Power	EXTRON 5: 4.8kW EXTRON 7: 15kW	15kW	Equivalent : The specifications have been enhanced to enable operation at power levels up to 4.8kW. That does not give rise to any novel concerns regarding safety and effectiveness.
X-ray tube	Rotating Anode	Rotating Anode	Identical
Radiographic Mode	kV Range : 40 to 120kV mA Range : Up to 150mA ※ EXTRON 7 only	kV Range : 40 to 120kV mA Range : Up to 125mA	Equivalent : Alteration in the mA does not give rise to any novel concerns regarding safety and effectiveness.
Fluoroscopic Mode	kV Range : 40 to 120kV mA Range : EXTRON 5 - Up to 40mA EXTRON 7 - Up to 60mA	kV Range : 40 to 120kV mA Range : 1 to 60mA	Equivalent : Alteration in the mA does not give rise to any novel concerns regarding safety and effectiveness.
Dimension	Immersion Depth : 74cm	Immersion Depth : 73cm	Equivalent :

	Free Space : 80cm Orbital movement : 165°	Free Space : 77cm Orbital movement : 145°	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	Identical
Foot Switch	Wired Foot Switch Wireless Foot Switch	Wired Foot Switch Wireless Foot Switch	Identical
Detector pixels	EXPD 2121P : 1500 x 1500 pixels EXPD 3030P : 2048 x 2048 pixels	1560 x 1420 pixels	Equivalent : Alteration in the detector pixels do not give rise to any novel concerns regarding safety and effectiveness.

The predicate devices (K142708) and the subject device, EXRON 5, EXTRON 7 are equivalent in terms of the following matters:

- Intended Use
- Target population
- Mobile Platform
- X-ray tube
- Laser Guide
- Foot Switch

A few differences are as follows:

- Max. Output Power
- Radiographic Mode
- Fluoroscopic Mode
- Dimension
- Detector pixels

There are no significant differences between the EXTRON 5 and EXTRON 7 and the predicate device that would have a negative impact on the product's use. Therefore, the subject device is considered substantially equivalent to the predicate device.

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

The EXTRON 5 and EXTRON 7 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
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
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 3.1 2013-10	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 2.1 2013-04	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 1.2 2018-06 CONSOLIDATED VERSION	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 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

And EXTRON 5 and EXTRON 7 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: Guidance for the Content of Premarket Submission for Software in Medical Devices	May 11, 2005
Guidance for Industry and Food and Drug Administration Staff: Medical X-Ray	May 8, 2019

Title of Guidance Document	Issue Date
Imaging Devices Conformance with IEC Standards	
Guidance for Industry and FDA Staff: Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices	July 11, 2016
Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices	February 3, 2016
Guidance for Industry and FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical devices	October 2, 2014

Phantom images of various body parts for both the proposed devices, EXTRON 5 and EXTRON 7, and the predicate device, Veradius Unity, have been taken. These images have been reviewed and compared by qualified clinical experts. As a result of this evaluation, it has been confirmed that the EXTRON 5 and EXTRON 7 devices provide equivalent image quality to the predicate device (Veradius Unity).

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

Not Applicable
Clinical studies were not performed, but phantom images were taken to support SE.

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

The EXTRON 5 and EXTRON 7 are substantially equivalent to the currently marketed predicate device (Veradius Unity (K142708)) in terms of design, fundamental scientific technology, and indications for use, safety, and effectiveness.

Substantial equivalence for Mobile fluoroscopic X-ray System(EXTRON 5, EXTRON 7) 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 60601-1-6, IEC 62366-1, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, IEC 60601-2-43, IEC 62304 and ANSI UL 2900-1.
The comparison of technological characteristics, non-clinical performance data and safety testing demonstrate that the EXTRON 5, EXTRON 7 are substantially equivalent to the predicate devices.