April 19, 2024

ulrich GmbH & Co. KG
% Rita King
Chief Executive Officer
MethodSense, Inc.
1 Copley Pkwy.
Suite 130
Morrisville, North Carolina 27560

Re: K233737
Trade/Device Name: ulricheasyINJECT Max 2M (XD 10140); ulricheasyINJECT Max 3 (XD 10150); ulricheasyINJECT Max 3 (XD 10180)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: November 21, 2023
Received: March 21, 2024

Dear Rita King:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233737

Device Name
ulricheasyINJECT Max 2M (XD 10140);
ulricheasyINJECT Max 3 (XD 10150);
ulricheasyINJECT Max 3 (XD 10180)

Indications for Use *(Describe)*

Indications for Use – ulricheasyINJECT Max System (Max 2M (XD 10140) and Max 3 (XD 10150))
ulricheasyINJECT Max System Max 2M (XD 10140) and Max 3 (XD 10150) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is specifically indicated for use in MRI procedures for the delivery of Clariscan (Gadoterate Meglumine) Injection, - GE Healthcare Inc. contrast media as supplied in approved single dose bottles.

Easy-Click-Cassette – flex Max 2M and Easy-Click-Cassette – flex Max 3 are used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or whichever comes first. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.

ulricheasyINJECT Max is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is not intended for injection of contrast media (CM) for high-pressure angiography.

Indications for Use – ulricheasyINJECT Max 3 (XD 10180)
ulricheasyINJECT Max 3 (XD 10180) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulricheasyINJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of VUEWAY™ (gadopiclenol), - Bracco Diagnostics Inc, MultiHance (gadobenate dimeglumine) – Bracco Diagnostics, Inc, Clariscan™ (Gadoterate Meglumine) Injection, - GE Healthcare Inc., Dotarem® (gadoterate meglumine) Injection – Guerbet, LLC, and Gadavist™ (gadobutrol) Injection, - Bayer HealthCare Pharmaceuticals Inc., contrast media as supplied in approved single dose vials.

Easy-Click-Cassette – flex Max 3 is used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or whichever comes first. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.

ulricheasyINJECT Max 3 (XD 10180) is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The ulricheasyINJECT Max 3 (XD 10180) is not intended for injection of contrast media (CM) for high-pressure angiography.

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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Summary of 510(k)

Ulrich GmbH & Co. KG K233737

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: ulrich GmbH & Co. KG
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Company Contact: Sven Erdmann
Vice President of Technology – Regulatory

Device Name and Classification

Trade Name: ulricheasyINJECT Max
Common Name: Contrast Media Management System
Classification: Class II
Regulation Number: 21 CFR 870.1650, Angiographic Injector and Syringe
Classification Panel: Cardiovascular Panel
Product Code: IZQ

Predicate Device:

	Predicate
Trade Name	ulrichINJECT CT motion
Common Name	Contrast Media Management System
510(k) Submitter / Holder	Class II
510(k) Number	K192872
Regulation Number	21 CFR 870.1650, Angiographic Injector and Syringe
Classification Panel	Cardiovascular Panel
Product Code	IZQ

The predicate device has not been subject to a design-related recall.

Device Description

ulricheasyINJECT Max is a syringeless contrast media management system that is designed for the controlled, automatic venous administration of contrast media in conjunction with physiological saline solution to human subjects undergoing diagnostic examinations in Magnetic Resonance Imaging (MRI or PET MRI).

The ulricheasyINJECT Max device consists of a terminal, injector, and tubing system. The injector is a mobile pedestal device that consists of an injector head and injector base with rechargeable battery. The tubing system is the only component that comes in contact with the patient and has indirect contact with the blood path of a patient for a limited duration (few minutes). The tubing system consists of the following three components:

- Spikes,

- Easy-Click-Cassette – flex
- Patient Tubing

The ulricheasyINJECT Max uses a peristaltic pump as part of the injector which is designed to transport the media fluid through the tubing system (spikes, cassette, and patient tubing). ulricheasyINJECT Max is intended to be used with the following components that are not supplied with the system:

- Saline containers,
- Single-dose contrast media bottles, and
- Cannula.

ulricheasyINJECT Max is equipped with multiple hardware and software controls that work together for the safe operation of the intended use of the system. Controls include air detectors to detect the presence of air in the tubing system without direct contact with the medium, pressure controls to manage and regulate pressure inside the tubing system, and check valves to prevent backflow of media and avoid retrograde contamination.

The ulricheasyINJECT Max is provided in three models:

- ulricheasyINJECT Max 2M (XD 10140),
- ulricheasyINJECT Max 3 (XD 10150), and
- ulricheasyINJECT Max 3 (XD 10180).

The Max 3 models have 3 media connection points: 1 NaCl and 2 Contrast Media connections. The Max 2M has 2 media connection points: 1 NaCl and 1 Contrast Media connections. Max 2M and Max 3 are technically identical except the different available media connection points.

Indications for Use

Indications for Use – ulricheasyINJECT Max System (Max 2M (XD 10140) and Max 3 (XD 10150))

ulricheasyINJECT Max System Max 2M (XD 10140) and Max 3 (XD 10150) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is specifically indicated for use in MRI procedures for the delivery of Clariscan (Gadoterate Meglumine) Injection, - GE Healthcare Inc. contrast media as supplied in approved single dose bottles.

Easy-Click-Cassette – flex Max 2M and Easy-Click-Cassette – flex Max 3 are used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or whichever comes first. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.

ulricheasyINJECT Max is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is not intended for injection of contrast media (CM) for high-pressure angiography.

Indications for Use – ulricheasyINJECT Max 3 (XD 10180)

ulricheasyINJECT Max 3 (XD 10180) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulricheasyINJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of VUEWAY™ (gadopiclenol), - Bracco Diagnostics Inc, MultiHance (gadobenate dimeglumine) – Bracco Diagnostics, Inc, Clariscan™ (Gadoterate Meglumine) Injection, - GE Healthcare Inc., Dotarem® (gadoterate meglumine) Injection – Guerbet, LLC, and Gadavist™ (gadobutrol) Injection, - Bayer HealthCare Pharmaceuticals Inc., contrast media as supplied in approved single dose vials.

Easy-Click-Cassette – flex Max 3 is used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or whichever comes first. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.

ulricheasyINJECT Max 3 (XD 10180) is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The ulricheasyINJECT Max 3 (XD 10180) is not intended for injection of contrast media (CM) for high-pressure angiography.

Predicate Device Comparison

ulricheasyINJECT Max is substantially equivalent to the ulrichINJECT CT Motion (K192872) by ulrich GmbH & Co. KG that is currently on the market.

Comparative Analysis of the ulricheasyINJECT Max to the Predicate Device

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Intended Use			
Intended Use	ulricheasyINJECT Max 2M (XD 10140) / 3 (XD 10150 / XD 10180) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations	ulrichINJECT CT motion is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations	Same
Indications for Use			
Indications for Use	**ulricheasyINJECT Max 2M (XD 10140) / 3 (XD 10150)** ulricheasyINJECT Max 2M (XD 10140) / 3 (XD 10150) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications. ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is specifically indicated for use in MRI procedures for the delivery of Clariscan (Gadoterate Meglumine) Injection, - GE Healthcare Inc. contrast media as supplied in approved single dose bottles. Easy-Click-Cassette – flex Max 2M and Easy-Click-Cassette – flex Max 3 are used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or whichever comes first. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling. Spike for MRI disposable is for single-bottle use only and must be discarded with the media	ulrichINJECT CT motion is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in computed tomography (CT) applications. ulrichINJECT CT motion is specifically indicated for use in CT procedures for the delivery of Omnipaque™ (Iohexol) Injection, solution - GE Healthcare Inc. contrast media as supplied in Imaging Bulk Packages (IBP), Omnipaque™ (Iohexol) Injection, solution - GE Healthcare Inc., and Visipaque™ (iodixanol) Injection - GE Healthcare Inc. contrast media as supplied in single dose bottles. Pump tubing-flex is used for a maximum time of twenty four (24) hours. When used with Omnipaque™ IBP, Omnipaque™ single dose bottles, or Visipaque™ single dose bottles, a maximum of 19 bottles of contrast media can be used or maximum time of twenty four (24) hours of Pump tubing-flex, or whichever comes first. Time per contrast media or saline container depends on each contrast media's or saline's use time expiration with a maximum	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through MR compatibility testing, chemical compatibility testing, and Safety / EMC testing.

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
	container. The Patient tubing must be discarded after each patient procedure. ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent. The ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150) is not intended for injection of contrast media (CM) for high-pressure angiography. **ulricheasyINJECT Max 3 (XD 10180)** ulricheasyINJECT Max 3 (XD 10180) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications. ulricheasyINJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of VUEWAY™ (gadopiclenol) Injection – Bracco Diagnostics, Inc., MultiHance (gadobenate dimeglumine) – Bracco Diagnostics, Inc, Clariscan™ (Gadoterate Meglumine) Injection, - GE Healthcare Inc., Dotarem® (gadoterate meglumine) Injection – Guerbet, LLC, and Gadavist™ (gadobutrol) Injection, - Bayer HealthCare Pharmaceuticals Inc., contrast media as supplied in approved single dose vials. Easy-Click-Cassette – flex Max 3 is used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or	of eight (8) hours per contrast media or saline container. Spike for CT disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure. ulrichINJECT CT motion is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.	

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
	whichever comes first. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling. Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure. ulricheasyINJECT Max 3 (XD 10180) is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent. The ulricheasyINJECT Max 3 (XD 10180) is not intended for injection of contrast media (CM) for high-pressure angiography.		
Product Codes			
Product Codes	IZQ (21 CFR 870.1650)	IZQ (21 CFR 870.1650)	Same
Device Use			
Environment of Use	MR Environment	CT Environment	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through MR compatibility testing, chemical compatibility testing, and Safety / EMC testing.
Physical			
System	Injector Head Touch Terminal	Injector Head Touch Terminal	Same

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Accessories	Injector Base	Injector Base; Wall Mount with moveable arm; Ceiling Mount with moveable arm; Contrast Media Housing with Heater	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through human factors validation.
Disposables	Easy-Click-Cassette 3 – flex Easy-Click-Cassette 2M – flex Patient tubing 250 cm Patient tubing 320 cm Patient tubing without RFID, 250 cm Patient tubing without RFID, 320 cm Spike for CT (CM/NaCl) and MRI (NaCl) Spike for MRI (CM) – holder l Spike for MRI (CM) – holder s	ulrichINJECT CT Motion Pump Tubing-flex Patient Tubing for Pump Tubing-flex ulrichINJECT CT Motion Spike	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through contamination control studies, chemical compatibility studies, and biocompatibility studies.
Weight	Injector: Approx. 40 kg Terminal: Approx. 3 kg	Injector (pedestal version): Approx. 80 kg Injector (ceiling and wall mount version): Approx. 40 kg Terminal: Approx. 3 kg	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through human factors validation.
Dimensions	Injector (with bottle holder): 53 cm x 53 cm x 137.2 cm Injector (with media rod): 530 mm x 530 mm x 1730 mm Terminal: 29.3 cm x 28.3 cm x 16 cm	Injector (pedestal version and wall mount version): 64.5 x 64.5 x 144.5 cm Injector (ceiling version): Depends on the system selected and the length of the fixed height arm Terminal: 31 x 27.5 x 17 cm	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through human factors validation.
Power Requirement	Rated Voltage: 100-240 V AC Rated Watts: 1.6 A / 200 W Rated Frequency: 50/60 Hz	Rated Voltage: 100-240 V AC Rated Current: 1.6 A Rated Frequency: 50/60Hz	Same
Battery	Li-Ion battery	Li-Ion battery	Same
Display Type	Color LCD Terminal with touch screen	Color LCD Terminal with touch screen	Same
Syringeless System	Yes	Yes	Same
Remote Operation	Yes, via the Touch Terminal	Yes, via the Touch Terminal	Same
Single Patient Use Disposable	Patient Tubing	Patient Tubing for Pump Tubing-flex	Same

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Designed to Prevent Reuse of Disposables	Yes – via the use of software controls and RFID	Yes – via the use of software controls	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.
Rotary peristaltic pump	Yes	Yes	Same
Used to administer contrast media and saline	Yes	Yes	Same
Disposable uses spikes to spike media container	Yes	Yes	Same
Safety Stop Mechanism	Multi-layered software stops; Used Patient Tubing detector and Cassette detector	Multi-layered software stops; Used Patient Tubing detector and Pump Tubing-flex detector	Same
Volume Remaining Readout	Yes, displayed on control unit at all times	Yes, displayed on control unit if programmed volume is higher than remaining volume	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed though software verification and validation and safety testing.
Programmable Pressure Limit	Yes, 159.5 PSI; user-programmable or automatic	Yes, 195 PSI; user-programmable or automatic	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.
Operational Characteristics			
Injection Capabilities	40 phases per protocol	40 phases per protocol	Same
Injection Rates for Contrast Media	0.1 mL/s to 10.0 mL/s	0.1 mL/s to 10.0 mL/s	Same
Injection Rates for Saline	0.1 mL/s to 10.0 mL/s	0.1 mL/s to 10.0 mL/s	Same

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Injection Volume per Injection	1 to 200 mL max volume of contrast media per patient with a max of 400 mL total media (contrast and saline) per patient	1 to 200 mL max volume of contrast media per patient with a max of 400 mL total media (contrast and saline) per patient	Same
Flow Rate and Volume Accuracy	10-400 mL of contrast media with volume accuracy of ± 5% Flow rate accuracy of ± 5%	10-200 mL of contrast media with volume accuracy of ± 5% Flow rate accuracy of ± 5%	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.
Contrast Media Container Volume	10–200 mL	500 mL (OMNIPAQUE IBP) 100 mL and 150 mL (VISIPAQUE single dose) 150 mL (OMNIPAQUE single dose)	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through contamination control, chemical compatibility, software safety, and software verification and validation testing.
Compatible Contrast Media	VUEWAY™ (gadopiclenol) single dose MultiHance (gadobenate dimeglumine) single dose Clariscan™ (Gadoterate Meglumine) single dose Dotarem® (gadoterate meglumine) single dose Gadavist™ (gadobutrol) single dose	OMNIPAQUE™ IBP OMNIPAQUE™ single dose VISIPAQUE™ single dose	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through chemical compatibility and extractables and leachables testing.
Saline Flush	Yes	Yes	Same
Needle Size	16-24 G	14-24 G	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Injection Pause	Programmable – 0 sec to 1800 sec in 1 sec increments	Programmable - 0 sec to 999 sec in 1 sec increments	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.
Injection Protocol Storage	Yes	Yes	Same
Priming/Venting Rate	4 mL/s	2 mL/s (manual)	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.
Air Detection Principle	Optical re-fraction sensor	Ultrasound	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.
Technical Detection Limit of air in tubing	0.05 mL	0.05 mL	Same
Air Detector Alarm Limit	1 mL	1 mL	Same
Occlusion Detection Principle	Fail safe piezo-resistive pressure sensor	Fail safe piezo-resistive pressure sensor	Same
Occlusion Detection Alarm Limit	203 PSI	246 PSI	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through software verification and validation and safety testing.

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Time Limit for Disposables	24 hours for Easy-Click-Cassette – flex 12 hours for Patient Tubing 24 hours for Spike	24 hours for Pump Tubing-flex 12 hours for Patient Tubing 8 hours for Spike for CT	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through contamination control, chemical compatibility, and extractables and leachables testing.
Package Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same
Packaging Configuration	Tyvek lid covering polystyrele tray	Tyvek lid covering polystyrele tray	Same
Patient Tubing Components	Patient Tubing One Luer Connector with safety cap One SafeConnect with safety cap Two check valves	Patient Tubing Two Patient Luer Connectors with safety caps Two check valves	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been evaluated via risk management activities and confirmed through contamination testing.
Contrast Media Line Tubing Material	PVC / PUR / polycarbonate	PVC / PUR	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been evaluated via risk management activities and confirmed through biocompatibility, chemical compatibility, and extractables / leachables testing.
Saline Line Tubing Material	PVC / PUR / polycarbonate	PVC / PUR	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been evaluated via risk management activities and confirmed through biocompatibility, chemical compatibility, and extractables / leachables testing.

Characteristic	Subject Device ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180) (K233737)	Predicate Device ulrichINJECT CT motion (K192872)	Comparison
Spike Length	Saline: 34.2 mm Contrast Media: 19.2 mm	28.5 mm	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulricheasyINJECT Max has been confirmed through bench testing and data

Non-Clinical Testing

ulricheasyINJECT Max system and software were validated in accordance with a Verification & Validation plan to ensure conformance with established performance criteria.

Software

Software verification and validation was performed.

Electromagnetic Compatibility / Electrical Safety Testing

Electromagnetic compatibility and electrical safety testing was performed following IEC 60601-1:2005, AMD 1:2012 and under compliance with the FDA recognized standard 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)].

Sterilization and Shelf Life

The ulricheasyINJECT Max System is ethylene oxide (EtO) sterilized and was validated to a SAL of 10^{-6}.

ISO 11135:2014 standard was used for sterilization process validation.

ulrich performed real time aging and accelerated aging studies. The ulricheasyINJECT Max tubing system was sterilized and its packaging was validated.

Verification results indicate that the ulricheasyINJECT Max tubing system complies with the standard. Additional testing performed includes transport validation.

Chemical Compatibility

Chemical Compatibility testing was performed to support the material compatibility of the ulricheasyINJECT Max tubing system with the following contrast media:

- Gadavist (gadobutrol) single dose,
- Clariscan™ (Gadoterate Meglumine) single dose bottle,
- VUEWAY™ (gadopiclenol) single dose bottle,
- MultiHance (gabobenate dimeglumine) single dose bottle, and
- Dotarem (gadoterate meglumine) single dose bottle.

Contamination Control

ulrich performed the following contamination control studies:

- Microbial ingress study, and
- Cross contamination study.

Based on these results, it has been concluded that ulricheasyINJECT Max has the ability to maintain the sterility of injection media and resist the ingress of microorganisms when used as intended. Additionally, it has been concluded that the residuals between the contrast media's active compounds after rinsing the system with physiological saline solution are within the defined limits.

Biocompatibility

The ulricheasyINJECT Max tubing system indirect patient contact materials were verified in accordance with the following standards:

- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Verification results indicated that the materials comply with the standard.

Performance – Bench

The ulricheasyINJECT Max tubing system was tested for performance and verified in accordance with the following standard:

- ISO 8536-4:2010, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed

ulricheasyINJECT tubing system is not a gravity feed device; therefore, only the applicable requirements from ISO 8536-4 were tested.

Test and verification results indicate that the ulricheasyINJECT Max tubing system conforms to its predetermined specifications and the applicable standards.

Extractables and Simulation

Additional testing was included extractables and simulation testing for leachable compounds.

Human Factors / Usability

Human Factors / Usability assessments were performed in a simulated use environment to optimize the device design and support the safe use of ulricheasyINJECT Max. The results demonstrated that users can operate ulricheasyINJECT Max as safely and effectively as the predicate device.

Conclusion

In conclusion, the intended use of the ulricheasyINJECT Max is the same as that of the predicate device (K192872). The difference between the predicate and subject device do not raise any new or different questions of safety and effectiveness. The non-clinical testing has demonstrated that the ulricheasyINJECT Max is substantially equivalent to the predicate device (K192872).