November 18, 2025

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

Re: K252281
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: October 22, 2025
Received: October 22, 2025

Dear Mrs. 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.

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant 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)*
K252281

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

Indications for Use *(Describe)*

ulricheasyINJECT Max 2M / 3 (XD 10140 / XD 10150)
ulricheasyINJECT Max 2M / 3 (XD 10140 / 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 the following contrast media:
• Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
• Gadopiclenol Injection in SD container or IBP
• Gadobenate dimeglumine Injection in SD container
• Gadoterate meglumine Injection in SD container

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, whichever comes first.

Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling.

Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the 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 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 the following contrast media:
• Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
• Gadopiclenol Injection in SD container or IBP
• Gadobenate dimeglumine Injection in SD container
• Gadoterate meglumine Injection in SD container

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, whichever comes first.

Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling.

Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the 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) K252281

ulrich GmbH & Co. KG

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

Submitter: ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
Germany

Primary Contact: Rita King
CEO
MethodSense, Inc.

Company Contact: Sven Erdmann
Vice President of Technology – Regulatory

Device Name and Classification

Trade Name: ulricheasyINJECT Max 2M (XD 10140); ulricheasyINJECT Max 3 (XD 10150); ulricheasyINJECT Max 3 (XD 10180)
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	ulrich**easy**INJECT Max 2M (XD 10140); ulrich**easy**INJECT Max 3 (XD 10150); ulrich**easy**INJECT Max 3 (XD 10180)
Common Name	Contrast Media Management System
510(k) Submitter / Holder	ulrich GmbH & Co. KG
510(k) Number	K241850
Classification	Class II
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

ulrich**easy**INJECT 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 ulrich**easy**INJECT 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 ulrich**easy**INJECT 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). ulrich**easy**INJECT Max is intended to be used with the following components that are not supplied with the system:

- Saline containers,
- Single-dose contrast media bottles,
- Imaging Bulk Package (IBP) contrast media containers, and
- Cannula.

ulrich**easy**INJECT 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 ulrich**easy**INJECT Max is provided in three models:

- ulrich**easy**INJECT Max 2M (XD 10140),
- ulrich**easy**INJECT Max 3 (XD 10150), and
- ulrich**easy**INJECT 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 – ulrich**easy**INJECT Max System (Max 2M (XD 10140) and Max 3 (XD 10150))

ulrich**easy**INJECT Max 2M / 3 (XD 10140 / 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.

ulrich**easy**INJECT Max 2M / 3 (XD 10140 / XD 10150) is specifically indicated for use in MRI procedures for the delivery of the following contrast media:

- Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
- Gadopiclenol Injection in SD container or IBP
- Gadobenate dimeglumine Injection in SD container
- Gadoterate meglumine Injection in SD container

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, whichever comes first.

Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling.

Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the 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.

ulrich**easy**INJECT 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.

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

Indications for Use – ulrich**easy**INJECT Max 3 (XD 10180)

ulrich**easy**INJECT 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.

ulrich**easy**INJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of the following contrast media:

- Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
- Gadopiclenol Injection in SD container or IBP
- Gadobenate dimeglumine Injection in SD container
- Gadoterate meglumine Injection in SD container

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, whichever comes first.

Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling.

Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the 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.

ulrich**easy**INJECT 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 ulrich**easy**INJECT Max 3 (XD 10180) is not intended for injection of contrast media (CM) for high-pressure angiography.

Predicate Device Comparison

ulrich**easy**INJECT Max is substantially equivalent to the ulrich**easy**INJECT Max (K241850) by ulrich GmbH & Co. KG that is currently on the market.

Comparative Analysis of the ulricheasyINJECT Max to the Predicate Device

Characteristic	Subject Device (K252281) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Predicate Device (K241850) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	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 in magnetic resonance (MR) applications.	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 in magnetic resonance (MR) applications.	Same
Indications for Use			
Indications for Use	**ulricheasyINJECT Max 2M (XD 10140) / 3 (XD 10150)** ulricheasyINJECT Max 2M / 3 (XD 10140 / 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 the following contrast media: • Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP) • Gadopiclenol Injection in SD container or IBP • Gadobenate dimeglumine Injection in SD container • Gadoterate meglumine Injection in SD container 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, whichever comes first.	**ulricheasyINJECT Max 2M (XD 10140) / 3 (XD 10150)** ulricheasyINJECT Max 2M / 3 (XD 10140 / 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., Gadavist (gadobutrol) Injection – Bayer HealthCare Pharmaceuticals Inc., VUEWAY™ (gadopiclenol) – Bracco Diagnostics, Inc., MultiHance (gadobenate dimeglumine) – Bracco Diagnostics, Inc., and Gadobutrol Injection – Fresenius Kabi AG, contrast media as supplied in approved single dose bottles and Gadavist (gadobutrol) Injection – Bayer HealthCare Pharmaceuticals Inc. and Gadobutrol Injection – Fresenius Kabi AG, contrast media as supplied in approved Imaging Bulk Packages (IBPs). 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, whichever comes first.	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 testing.

Characteristic	Subject Device (K252281) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Predicate Device (K241850) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Comparison
	Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling. Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the 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 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 the following contrast media: • Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP) • Gadopiclenol Injection in SD container or IBP	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. Use time expiration per IBP contrast media container is a maximum of twenty-four (24) 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 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. 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 –	

Characteristic	Subject Device (K252281) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Predicate Device (K241850) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Comparison
	• Gadobenate dimeglumine Injection in SD container • Gadoterate meglumine Injection in SD container 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, whichever comes first. Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling. Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the 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.	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.	
Product Codes			
Product Codes	IZQ (21 CFR 870.1650)	IZQ (21 CFR 870.1650)	Same
Device Use			
Environment of Use	MR Environment	MR Environment	Same

Characteristic	Subject Device (K252281) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Predicate Device (K241850) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Comparison
Physical			
System	Injector Head Touch Terminal	Injector Head Touch Terminal	Same
Accessories	Injector Base	Injector Base	Same
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	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	Same
Weight	Injector: Approx. 40 kg Terminal: Approx. 3 kg	Injector: Approx. 40 kg Terminal: Approx. 3 kg	Same
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 (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	Same
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 Watts: 1.6 A / 200 W Rated Frequency: 50/60 Hz	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	Same
Designed to Prevent Reuse of Disposables	Yes – via the use of software controls and RFID	Yes – via the use of software controls and RFID	Same
Rotary peristaltic pump	Yes	Yes	Same
Used to administer contrast media and saline	Yes	Yes	Same

Characteristic	Subject Device (K252281) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Predicate Device (K241850) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Comparison
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 Cassette detector	Same
Volume Remaining Readout	Yes, displayed on control unit at all times	Yes, displayed on control unit at all times	Same
Programmable Pressure Limit	Yes, 159.5 PSI; user-programmable or automatic	Yes, 159.5 PSI; user-programmable or automatic	Same
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
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%	10-400 mL of contrast media with volume accuracy of ± 5% Flow rate accuracy of ± 5%	Same
Contrast Media Container Volume	10–200 mL	10–200 mL	Same
Compatible Contrast Media	Gadopiclenol Injection in SD container Gadobenate dimeglumine Injection in SD container Gadoterate meglumine Injection in SD container Gadobutrol Injection in SD container Gadobutrol Injection in IBP Gadopiclenol Injection in IBP	VUEWAY™ (gadopiclenol) single dose MultiHance (gadobenate dimeglumine) single dose Clariscan™ (Gadoterate Meglumine) single dose Dotarem® (gadoterate meglumine) single dose Gadavist™ (gadobutrol) single dose Gadobutrol single dose Gadavist™ (gadobutrol) IBP Gadobutrol IBP	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 rinsing testing.
Saline Flush	Yes	Yes	Same
Needle Size	16-24 G	16-24 G	Same
Injection Pause	Programmable – 0 sec to 1800 sec in 1 sec increments	Programmable – 0 sec to 1800 sec in 1 sec increments	Same
Injection Protocol Storage	Yes	Yes	Same

Characteristic	Subject Device (K252281) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Predicate Device (K241850) ulricheasyINJECT Max (XD 10140 / XD 10150 / XD 10180)	Comparison
Priming/Venting Rate	4 mL/s	4 mL/s	Same
Air Detection Principle	Optical re-fraction sensor	Optical re-fraction sensor	Same
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	203 PSI	Same
Time Limit for Disposables	24 hours for Easy-Click-Cassette – flex 12 hours for Patient Tubing 24 hours for Spike	24 hours for Easy-Click-Cassette – flex 12 hours for Patient Tubing 24 hours for Spike	Same
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 One Luer Connector with safety cap One SafeConnect with safety cap Two check valves	Same
Contrast Media Line Tubing Material	PVC / PUR / polycarbonate	PVC / PUR / polycarbonate	Same
Saline Line Tubing Material	PVC / PUR / polycarbonate	PVC / PUR / polycarbonate	Same
Spike Length	Saline: 34.2 mm Contrast Media: 19.2 mm	Saline: 34.2 mm Contrast Media: 19.2 mm	Same

Non-Clinical Testing

ulrich**easy**INJECT 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 as part of K241850 and has been repeated for the software updates made as part of this submission. These activities have been performed in accordance with IEC 62304:2015 Medical device software - Software life cycle processes.

Cybersecurity

ulrich performed cybersecurity testing for the ulrich**easy**INJECT Max system in accordance with FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 27, 2025*).

Electromagnetic Compatibility / Electrical Safety Testing

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact EMC or electrical safety of the device or its components. Therefore, all previously conducted testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

Electromagnetic compatibility and electrical safety testing was performed in accordance with the following standard as part of K241850:

- IEC 60601-1:2005, AMD 1:2012, AMD 2:2020 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 Validation

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact sterilization of the device's components. Therefore, all previously conducted testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

The ulrich**easy**INJECT Max System is ethylene oxide (EtO) sterilized and was validated to a sterility assurance level of 10^{-6} as part of K233737.

Shelf Life and Transport Validation

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact shelf life or transport validation of the device or its components. Therefore, all previously conducted testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

Real-time aging and accelerated aging studies were performed as part of K233737. The ulrich**easy**INJECT Max tubing system is sterilized and its packaging was validated.

ulrich performed transport validation on the ulrich**easy**INJECT Max tubing system, injector, and terminal as part of K233737.

Chemical Compatibility

In addition to Chemical Compatibility testing performed in support of K241850 and K233737, additional Chemical Compatibility testing was performed to support the material compatibility of the ulrich**easy**INJECT Max tubing system with the following contrast media:

- Gadopiclenol IBP

Contamination Control and Rinsing

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact potential contamination pathways of the device or its components. Therefore, all previously conducted contamination control testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

ulrich performed Contamination Control and Rinsing Studies for the ulrich**easy**INJECT Max as part of K233737.

- A **microbial ingress study** demonstrated the ability of the ulrich**easy**INJECT Max system to prevent the ingress of microorganisms during use.
- A **cross contamination study** demonstrated the effectiveness of the tubing system in preventing contamination from one patient to another.
- A **rinsing study** demonstrated that the residuals of the single active compounds after rinsing the system with physiological saline solution are within the defined limits.

MR Compatibility

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact MR compatibility of the device or its components. Therefore, all previously conducted testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

ulrich performed MR Compatibility testing in accordance with FDA *Guidance for Industry and Food and Drug Administration Staff: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (October 2023)* as part of K241850 and K233737.

Biocompatibility

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact biocompatibility of the device or its components. Therefore, all previously conducted testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

The ulrich**easy**INJECT Max tubing system indirect patient contact materials were verified in accordance with the following standard as part of K233737:

- 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 changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact the performance testing of the device or its components under ISO 8536-4. Therefore, all previously conducted testing per ISO 8536-4 remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

The ulrich**easy**INJECT Max tubing system was tested for performance and verified in accordance with the following standard as part of K233737:

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

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

Test and verification results indicated that the ulrich**easy**INJECT Max tubing system conforms to its predetermined specifications and the applicable standards.

Extractables and Simulation

Additional testing included extractables and simulation testing for leachable compounds as part of K241850 and K233737. All previously conducted testing for indicated contrast media remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

Human Factors / Usability

The changes made to the ulrich**easy**INJECT Max system as part of this submission do not impact the critical tasks associated with use of the device or its components. Therefore, all previously conducted Human Factors / Usability testing remains applicable and sufficient to demonstrate continued compliance with FDA-recognized consensus standards.

A usability study was performed as part of K233737 to confirm that the ulrich**easy**INJECT Max is safe and effective for use by its intended users.

Conclusion

In conclusion, the intended use of the ulrich**easy**INJECT Max is the same as that of the predicate device (K241850). The differences 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 ulrich**easy**INJECT Max is substantially equivalent to the predicate device (K241850).