November 7, 2025

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

Re: K251295
Trade/Device Name: ulrichINJECT CT Motion (XD 8000)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: October 6, 2025
Received: October 6, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kyran R. Gibson -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)*
K251295

Device Name
ulrichINJECT CT Motion (XD 8000)

Indications for Use *(Describe)*
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 the following contrast media:
• Iohexol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
• Iodixanol Injection in SD container
• Iopamidol Injection in IBP

Pump tubing – flex can be used with a maximum of 36 bottles of contrast media or a maximum time of twenty-four (24) hours, whichever comes first.

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

Use time expiration per IBP is limited to a maximum time stated by the specific contrast media labeling.

Use time expiration per saline container is a maximum of twenty four (24) hours from initial puncture.

Spike for CT disposable is for single-bottle use only and must be discarded with the media container. The maximum time usage for the Spike for CT is twenty four (24) hours, or the maximum use time for the contrast media container indicated for use with ulrichINJECT CT motion, whichever comes first.

The Patient tubing must be discarded after each patient procedure.

SYNCopen is indicated for the specific purpose of allowing an injector to interface with a CT scanner.

RIS/PACS is indicated for the specific purpose of allowing an injector to interface with a Radiological Information System (RIS) and a Picture Archiving and Communications System (PACS).

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 media.

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) K251295

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: ulrichINJECT CT motion
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	ulrich GmbH & Co. KG
510(k) Number	K210541
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

ulrichINJECT CT motion is a syringeless contrast media management system that is designed for the controlled, automatic administration, on the venous side, of contrast media and saline, to human subjects undergoing diagnostic examinations in computed tomography (CT) applications.

The ulrichINJECT CT motion system consists of a terminal, injector, and tubing system. 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 (<24 hours). The tubing system consists of the following three (3) components:

- Spike for CT (CM/NaCl);
- Pump tubing – flex; and
- Patient Tubing.

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

- Saline containers,

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

ulrichINJECT CT motion 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 ulrichINJECT CT motion is provided in two versions:
- Mobile pedestal version
- Ceiling version

The mobile pedestal version consists of the injector head and the injector base with rechargeable battery. The ceiling version consists of the injector head, a fixed-height arm, and a movable arm.

Indications for Use

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 the following contrast media:
- Iohexol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
- Iodixanol Injection in SD container
- Iopamidol Injection in IBP

Pump tubing – flex can be used with a maximum of 36 bottles of contrast media or a maximum time of twenty-four (24) hours, whichever comes first.

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

Use time expiration per IBP is limited to a maximum time stated by the specific contrast media labeling.

Use time expiration per saline container is a maximum of twenty four (24) hours from initial puncture.

Spike for CT disposable is for single-bottle use only and must be discarded with the media container. The maximum time usage for the Spike for CT is twenty four (24) hours, or the maximum use time for the contrast media container indicated for use with ulrichINJECT CT motion, whichever comes first.

The Patient tubing must be discarded after each patient procedure.

SYNCopen is indicated for the specific purpose of allowing an injector to interface with a CT scanner.

RIS/PACS is indicated for the specific purpose of allowing an injector to interface with a Radiological Information System (RIS) and a Picture Archiving and Communications System (PACS).

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 media.

Predicate Device Comparison

ulrichINJECT CT motion is substantially equivalent to the ulrichINJECT CT motion (K210541) by ulrich GmbH & Co. KG that is currently on the market.

Comparative Analysis of the ulrichINJECT CT motion to the Predicate Device

Item	Subject Device ulrichINJECT CT motion (K251295)	Predicate Device ulrichINJECT CT motion (K210541)	Comparison
Intended Use	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 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.	Same
Indications for Use	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 the following contrast media: • Iohexol Injection in single-dose (SD) container or Imaging Bulk Package (IBP) • Iodixanol Injection in SD container • Iopamidol Injection in IBP Pump tubing – flex can be used with a maximum of 36 bottles of contrast media or a maximum time of twenty-four (24) hours, whichever comes first. Use time expiration per SD container is a maximum of four (4) hours from initial puncture, unless otherwise stated by the contrast media labeling. Use time expiration per IBP is limited to a maximum time stated by the specific contrast media labeling. Use time expiration per saline container is a maximum of twenty four (24) hours from initial puncture.	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 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	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulrichINJECT CT motion has been confirmed through chemical compatibility and contamination control testing.

Item	Subject Device ulrichINJECT CT motion (K251295)	Predicate Device ulrichINJECT CT motion (K210541)	Comparison
	Spike for CT disposable is for single-bottle use only and must be discarded with the media container. The maximum time usage for the Spike for CT is twenty four (24) hours, or the maximum use time for the contrast media container indicated for use with ulrichINJECT CT motion, whichever comes first. The Patient tubing must be discarded after each patient. SYNCopen is indicated for the specific purpose of allowing an injector to interface with a CT scanner. RIS/PACS is indicated for the specific purpose of allowing an injector to interface with a Radiological Information System (RIS) and a Picture Archiving and Communications System (PACS). 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 media.	after each patient procedure. SYNCopen is indicated for the specific purpose of allowing an injector to interface with a CT scanner. RIS/PACS is indicated for the specific purpose of allowing an injector to interface with a Radiological Information System (RIS) and a Picture Archiving and Communication System (PACS). 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.	
System	Injector Head Touch Terminal	Injector Head Touch Terminal	Same
Accessories	Injector Base (pedestal) Ceiling Mount with moveable arm Contrast Media Housing with Heater Media label reader	Injector Base (pedestal)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 ulrichINJECT CT motion has been confirmed through verification and validation testing.
Disposables	ulrichINJECT CT Motion Pump Tubing-flex Patient Tubing for Pump Tubing-flex ulrichINJECT CT Motion Spike for CT	ulrichINJECT CT Motion Pump Tubing-flex Patient Tubing for Pump Tubing-flex ulrichINJECT CT Motion Spike for CT	Same
Weight	Injector (pedestal version): Approx. 80 kg Injector (ceiling version): 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	Same

Item	Subject Device ulrichINJECT CT motion (K251295)	Predicate Device ulrichINJECT CT motion (K210541)	Comparison
Dimensions	Injector (pedestal 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	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	Same
Power Requirement	Rated Voltage: 100 to 240 V AC Rated Current: 1.6 A Rated Frequency: 50/60Hz	Rated Voltage: 100 to 240 V AC Rated Current: 1.6 A Rated Frequency: 50/60Hz	Same
Battery	Lead gel battery or Li-Ion battery	Lead gel battery or 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 for Pump Tubing-flex	Patient Tubing for Pump Tubing-flex	Same
Designed to Prevent Reuse of Disposables	Yes – via the use of software controls	Yes – via the use of software controls	Same
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 Pump Tubing-flex detector	Multi-layered software stops; Used Patient Tubing detector and Pump Tubing-flex detector	Same
Volume Remaining Readout	Yes, displayed on control unit if programmed volume is higher than remaining volume A traffic light feature is included to better indicate remaining media volume on the GUI.	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 ulrichINJECT CT motion has been confirmed through verification and validation testing.
Programmable Pressure Limit	Yes, 195 PSI; user-programmable or automatic	Yes, 195 PSI; user-programmable or automatic	Same

Item	Subject Device ulrichINJECT CT motion (K251295)	Predicate Device ulrichINJECT CT motion (K210541)	Comparison
Injector-Scanner Interface	SYNCopen functionality allows start of the injector and CT scanner simultaneously and communicates information from the CT motion to the CT scanner.	SYNCopen functionality allows start of the injector and CT scanner simultaneously and communicates information from the CT motion to the CT scanner.	Same
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	10-200 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%	Same
Contrast Media Container Volume	100mL – 500mL	100mL – 500mL	Same
Compatible Contrast Media	Iohexol Injection in IBP Iohexol Injection in SD container Iodixanol Injection in SD container Iopamidol Injection in IBP	OMNIPAQUE™ (Iohexol) IBP OMNIPAQUE™ (Iohexol) single dose VISIPAQUE™ (Iodixanol) single dose	Different - This difference does not change the intended use of the device. The safety and effectiveness of the ulrichINJECT CT motion has been confirmed through chemical compatibility testing.
Saline Flush	Yes	Yes	Same
Needle Size	14-24 G	14-24 G	Same
Injection Pause	Programmable - 0 sec to 999 sec in 1 sec increments	Programmable - 0 sec to 999 sec in 1 sec increments	Same
Injection Protocol Storage	Yes	Yes	Same
Priming/Venting Rate	2 mL/s (manual)	2 mL/s (manual)	Same
Air Detection Principle	Ultrasound	Ultrasound	Same
Technical Detection Limit of air in tubing	0.05 mL	0.05 mL	Same

Item	Subject Device ulrichINJECT CT motion (K251295)	Predicate Device ulrichINJECT CT motion (K210541)	Comparison
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	246 PSI	246 PSI	Same
Time Limit for Disposables	24 hours for ulrichINJECT CT Motion Pump Tubing-flex 12 hours for Patient Tubing for Pump Tubing-flex 24 hours for ulrichINJECT CT Motion Spike for CT	24 hours for ulrichINJECT CT Motion Pump Tubing-flex 12 hours for Patient Tubing for Pump Tubing-flex 8 hours for ulrichINJECT CT Motion Spike for CT	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 Two Patient Luer Connectors with safety caps Two check valves	Patient Tubing Two Patient Luer Connectors with safety caps Two check valves	Same
Safety Feature Against Re-use	Yes, via software controls	Yes, via software controls	Same
Pump-Tubing Flex Components	Contrast media lines x2 Saline Line W-piece Pressure sensor unit with integrated particle filter Check valve Swabable valves x 4	Contrast media lines x2 Saline Line W-piece Pressure sensor unit with integrated particle filter Check valve Swabable valves x 4	Same
Contrast Media Line Tubing Material	PVC / PUR	PVC / PUR	Same
Saline Line Tubing Material	PVC / PUR	PVC / PUR	Same
Spike Size	PVC / PUR	PVC / PUR	Same
Safety Feature Against Re-Use	Yes, via software controls	Yes, via software controls	Same

Non-Clinical Testing

ulrichINJECT CT motion 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 K171392, K192872, and K210541 and has been repeated for the software updates made as part of this submission.

Cybersecurity

ulrich performed cybersecurity testing for the ulrichINJECT CT motion system in accordance with FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023)*.

Electromagnetic Compatibility / Electrical Safety Testing

Electromagnetic compatibility and electrical safety testing was performed in accordance with the following standard:

- 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 ulrichINJECT CT motion tubing system is ethylene oxide (EtO) sterilized and was validated in accordance with ISO 11135:2014 to a sterility assurance level of 10^{-6} as part of K171392, K192872, and K210541.

Shelf Life and Transport Validation

Real-time aging studies were performed wherein the ulrichINJECT CT motion tubing system was sterilized and its packaging was validated.

ulrich performed transport validation on the ulrichINJECT CT motion tubing system, injector, and terminal.

Chemical Compatibility

In addition to Chemical Compatibility testing performed in support of K171392 and K192872, additional Chemical Compatibility testing was performed to support the material compatibility of the ulrichINJECT CT motion tubing system with Iopamidol Injection in IBPs.

Contamination Control and Rinsing

In addition to contamination control testing performed in support of K171392 and K192872, ulrich performed the following Contamination Control Studies for the ulrichINJECT CT motion:

- A **microbial ingress study** demonstrated the ability of the ulrichINJECT CT motion system to prevent the ingress of microorganisms during use up to 24 hours or a maximum of 36 bottles.

Biocompatibility

The ulrichINJECT CT motion tubing system indirect patient contact materials were verified in accordance with the following standards as part of K171392 and K192872:

- 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.

Reprocessing

Cleaning and disinfection validation testing was completed in accordance with FDA guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* and the following standards:

- ANSI/AAMI ST98:2022,
- AAMI TIR30:2011/(R)2016,
- AAMI TIR12:2020/(R)2023, and
- ISO 17664-2:2021

Testing was performed to demonstrate the compatibility and durability of the ulrichINJECT CT motion with cleaning agents and disinfectants.

Performance – Bench

The ulrichINJECT CT motion tubing system was tested for performance and verified in accordance with the following standard as part of K171392:

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

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

Testing was also performed as part of K192872 to confirm that mixing of contrast media will not occur.

Test and verification results indicated that the ulrichINJECT CT motion tubing system conforms to its predetermined specifications and the applicable standards.

Extractables and Simulation

Simulation testing was performed for leachable compounds with Iopamidol as a part of this submission. Additionally, testing was previously performed for extractables and simulation testing for leachable compounds with Iohexol and Iodixanol as a part of K192872.

Human Factors / Usability

In addition to usability studies performed as part of K171392, usability evaluations, including a usability study, were performed as part of this submission to confirm that the updated ulrichINJECT CT motion system with additional software options remains safe and effective for use by the intended user population.

Conclusion

In conclusion, the intended use of the ulrichINJECT CT motion is the same as that of the predicate device (K210541). 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 ulrichINJECT CT motion is substantially equivalent to the predicate device (K210541).