August 6, 2021

ulrich GmbH & Co. KG
% Rita King
CEO
MethodSense Inc.
1 Copley Parkway, Suite 410
Morrisville, North Carolina 27560

Re: K210541
Trade/Device Name: ulrichINJECT CT motion
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: July 8, 2021
Received: July 9, 2021

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

CAPT Alan M. Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210541

Device Name
ulrichINJECT CT motion

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 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, solution - 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 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 agent.

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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510(k) Summary

ulrich GmbH & Co. KG K210541

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

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Date Prepared: August 6, 2021

Device Name and Classification

Trade Name: ulrichINJECT CT motion
Common Name: Contrast Media Management System
Classification: Class II
Regulation Number: 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	K192872
Classification	Class II
Regulation Number	CFR 870.1650, Angiographic Injector and Syringe
Classification Panel	Cardiovascular Panel
Product Code	IZQ

Reference Device	
Trade Name	MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, MEDRAD Stellant FLEX Syringe Kits, MEDRAD Stellant CT Injection System with Certegra Workstation, MEDRAD Stellant Syringe Kits, MEDRAD Stellant Connector Tubing, P3T Cardiac, P3T PA, P3T Abdomen, ISI, Connect.CT
Common Name	Injector And Syringe, Angiographic
510(k) Submitter / Holder	Bayer Medical Care, Inc.
510(k) Number	K182273
Classification	Class II
Regulation Number	CFR 870.1650
Classification Panel	Cardiovascular
Product Code	DXT

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 the CT motion terminal, CT motion injector, and the CT motion tubing system. The CT motion 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 CT motion tubing system consists of three components:

- Spike for CT
- Pump tubing-flex
- Patient Tubing

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

- Multiple patient use saline containers,
- Omnipaque IBP contrast media containers,
- Omnipaque single-dose contrast media bottles,
- Visipaque single-dose contrast media bottles, and
- Cannula.

The ulrichINJECT CT motion system 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.

ulrichINJECT CT motion is equipped with multiple hardware and software controls that work together for the safe operation of the intended use of the device. Controls include air detectors, which are designed to detect air 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 three versions:

- Mobile pedestal version
- Ceiling version
- Wall mounted version

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

The software option SYNCopen is a new software and hardware option which allows a connection between the injector system and a validated CT scanner. Both systems can communicate with each other and thus synchronize time sequences. The software option is only

available if the manufacturer of the CT scanner has enabled the connection to the injector system.

The ulrich medical RIS/PACS Interface is a new software option supports transferring documentation-related parameters for a contrast media injection to healthcare IT systems. A worklist can be retrieved from a RIS server by means of the DICOM modality worklist information model. After selecting a patient from the worklist and performing the injection, a comprehensive contrast media dose report is automatically transmitted to the configured PACS and/or Dose Reporting system.

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 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 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.

Risk Analysis Method

The ulrichINJECT CT motion was assessed to determine the risks to health associated with the use of the syringeless injector. A risk analysis was conducted in accordance with ISO

14971:2007, Medical devices – Application of risk management to medical devices. Several risks were assessed, including, but not limited to, device malfunction, contamination and infection, and improper use.

Substantial Equivalence

The ulrichINJECT CT motion is substantially equivalent to the predicate, *ulrichINJECT CT motion* (K192872) currently on the market. The table below provides a detailed comparison of ulrichINJECT CT motion to the predicate device.

Additionally, the ulrichINJECT CT motion SYNCopen component is substantially equivalent to the reference device, *MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, MEDRAD Stellant FLEX Syringe Kits, MEDRAD Stellant CT Injection System with Certegra Workstation, MEDRAD Stellant Syringe Kits, MEDRAD Stellant Connector Tubing, P3T Cardiac, P3T PA, P3T Abdomen, ISI, Connect.CT* (K182273), ISI component. The reference device (K182273) ISI functionality allows start of the injector and CT scanner simultaneously and communicates information between the injector and CT scanner, similar to the ulrichINJECT CT motion SYNCopen functionality.

Detailed Comparison of the Subject and Predicate Device

Item	Subject Device ulrichINJECT CT motion	Primary Predicate ulrichINJECT CT motion (K192872)	Comparison
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 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.	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.	Similar. See Note 1.

Item	Subject Device ulrichINJECT CT motion	Primary Predicate ulrichINJECT CT motion (K192872)	Comparison
	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. 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.	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.	
System	Injector Head Touch Terminal	Injector Head Touch Terminal	Same
Accessories	Injector Base Wall Mount with moveable arm Ceiling Mount with moveable arm Contrast Media Housing with Heater	Injector Base Wall Mount with moveable arm Ceiling Mount with moveable arm Contrast Media Housing with Heater	Same

Item	Subject Device ulrichINJECT CT motion	Primary Predicate ulrichINJECT CT motion (K192872)	Comparison
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 and wall mount 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
Dimensions	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	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	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

Item	Subject Device ulrichINJECT CT motion	Primary Predicate ulrichINJECT CT motion (K192872)	Comparison
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	Yes, displayed on control unit if programmed volume is higher than remaining volume	Same
Programmable Pressure Limit	Yes, 195 PSI; user-programmable or automatic	Yes, 195 PSI; user-programmable or automatic	Same
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.	Not available.	Different. See Note 2.
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

Item	Subject Device ulrichINJECT CT motion	Primary Predicate 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	10-200 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	500 mL (OMNIPAQUE IBP) 100 mL and 150 mL (VISIPAQUE single dose) 150 mL (OMNIPAQUE single dose)	500 mL (OMNIPAQUE IBP) 100 mL and 150 mL (VISIPAQUE single dose) 150 mL (OMNIPAQUE single dose)	Same
Compatible Contrast Media	OMNIPAQUE™ IBP OMNIPAQUE™ single dose VISIPAQUE™ single dose	OMNIPAQUE™ IBP OMNIPAQUE™ single dose VISIPAQUE™ single dose	Same
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

Item	Subject Device ulrichINJECT CT motion	Primary Predicate ulrichINJECT CT motion (K192872)	Comparison
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	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 8 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
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

Item	Subject Device ulrichINJECT CT motion	Primary Predicate ulrichINJECT CT motion (K192872)	Comparison
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	28.5 mm	28.5 mm	Same
Safety Feature Against Re-Use	Yes, via software controls	Yes, via software controls	Same

Note 1. The Indications for Use related to contrast media management and the disposable components of the CT motion are identical to the Indications for Use of the previously cleared ulrichINJECT CT motion (K192872). The ulrichINJECT CT motion's Indications for Use as it relates to new SYNCopen functionality and new Class I, 510(k) exempt Indications related to interfacing with RIS and PACS systems are different from the predicate device (K192872). The introduction of SYNCopen and RIS/PACS functionality in the indications for use does not raise any questions of safety and effectiveness as software verification and validation and safety testing have been performed to confirm the device remains as safe and effective as the predicate device (K192872).

Note 2. The injector scanner interface (SYNCopen) is a new functionality that was not present on the previously cleared ulrichINJECT CT motion (K192872). The introduction of SYNCopen functionality does not raise any questions of safety and effectiveness as software verification and validation and safety testing have been performed to confirm the device remains as safe and effective as the predicate device (K192872).

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 and K192872 and has been repeated for the software updates made as part of this submission. FDA's guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry and FDA Staff" (2005) has been followed.

Validation included installation qualification and operational performance qualification. All acceptance criteria for the installation qualification and operational and performance qualification are satisfactorily met so that the ulrichINJECT CT motion software is released for its intended use.

Electromagnetic Compatibility / Electrical Safety**:**

Testing was performed in accordance with the following standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; Edition 3.1 (2012)
- IEC 60601-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests; Edition 4.0 (2014)

Testing results indicate that the ulrichINJECT CT motion complies with the standards listed.

Sterilization:

The ulrichINJECT CT motion tubing system is ethylene oxide (EtO) sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standard prior to commercial distribution as part of K192872:

- ISO 11135-1: Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices; 2007

Verification results indicate that the ulrichINJECT CT motion tubing system complies with the standard.

Shelf-Life:

Real-time aging and accelerated-aging studies were performed as part of K171392 and K192872. The ulrichINJECT CT motion tubing system is sterilized and its packaging was validated in accordance with the following standard:

- ISO 11607-1: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems; 2006

Verification results indicate that the ulrichINJECT CT motion tubing system complies with the standard for a shelf life of 5 years.

Chemical Compatibility:

Material compatibility of the ulrichINJECT CT motion tubing system was performed as part of K192872 using Omnipaque™ and Visipaque™ as the solvents. The results of the testing concluded that the ulrichINJECT CT motion tubing system does not interact with Omnipaque™ or Visipaque™ and the chemical integrity of Omnipaque™ or Visipaque™ is not compromised throughout use. Therefore, ulrichINJECT CT motion is safe and effective for its intended uses.

Contamination Control:

ulrich performed the following contamination control studies as part of K192872:

- Process Simulation Studies
- Microbial Ingress Study
- Cross Contamination Study
- Rinsing Study

Contamination control study results have concluded that ulrichINJECT CT motion has the ability to maintain the sterility of the injection media and resist the ingress of microorganisms when used with Omnipaque™ Imaging Bulk Package (IBP), Omnipaque single dose bottles, and Visipaque single dose bottles during its intended use. Additionally, it has been concluded that the residuals between the single active compounds (Iohexol and Iodixanol) after rinsing the system with physiological saline solution are within the defined limits.

Biocompatibility:

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

- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; 2009

The following tests have been performed:

- Cytotoxicity
- Intracutaneous reactivity
- Allergic sensitization
- Systemic acute toxicity
- Pyrogen shelf-life:
- Hemocompatibility: Hemolysis
- LAL test: Bacterial endotoxins

Verification results indicated that the materials comply with the standard.

Extractables and Leachables:

Testing was performed for extractables and simulation testing for leachable compounds and particulates as part of K171392 and K192872 for OMNIPAQUE and VISIPAQUE.

Testing and a toxicological assessment demonstrated that ulrichINJECT CT motion is safe and effective for its intended uses. The results of the testing and toxicological assessment met the requirements of the pre-defined acceptance criteria for the intended uses of the device.

Human Factors:

A usability study was performed as part of K171392 to confirm that the ulrichINJECT CT motion was safe and effective for use by its intended users. Usability evaluations, including a usability study, were performed as part of K210541 to confirm that the updated ulrichINJECT CT motion system with RIS/PACS and SYNCopen software options is still safe and effective for use by the intended user population. Results demonstrated that no new unacceptable usability risks were introduced by the modifications and the intended user population is able to perform use tasks.

Performance – Bench:

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

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

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

Transport validation and cleaning instructions validation was also performed as part of K171392.

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

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

Conclusion

Based on the performance testing, comparison, and analysis in this submission, the subject device, ulrichINJECT CT motion, is substantially equivalent to the predicate device, K192872.