July 2, 2020

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

Re: K192872
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: May 29, 2020
Received: June 2, 2020

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,

For CAPT Alan 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Summary of 510(k)

Ulrich GmbH & Co. KG

K192872

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

Submitter: ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
Germany
Phone: +49 731 9654-1714
Fax: +49 731 9654-2807

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: 919-313-3961
Fax: 919-313-3979

Company Contact: Sven Erdmann
Director Development & Product Management Devices

Date Prepared: May 29, 2020

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	Class II
510(k) Number	K171392
Regulation Number	21 CFR 870.1650, Angiographic Injector and Syringe
Classification Panel	Cardiovascular Panel
Product Code	IZQ

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 updated 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 updated 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 and has been updated to operate with a rechargeable Li-ion battery or lead gel battery in addition to the power supply. The ceiling version and the wall mounted version consist 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 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.

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 updated ulrichINJECT CT motion system was assessed to determine the risks to health associated with the use of the device specifically as it relates to the use of OMNIPAQUE and VISIPAQUE single dose bottles and the new Li-ion battery. Risks related to safety, contamination and usability were considered. 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, mixing of contrast media, contamination and infection, and improper use.

Substantial Equivalence

ulrichINJECT CT motion is substantially equivalent to the ulrichINJECT CT motion system (K171392) currently on the market.

The table below provides a detailed comparison of ulrichINJECT CT motion to the predicate device.

Detailed Comparison of the Subject and Predicate Device

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	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	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, 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). Pump tubing-flex is used for a maximum time of twenty four (24) hours. When used with Omnipaque™ IBP, 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, 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.	The intended use of the ulrichINJECT CT motion is identical to the intended use of the previously cleared ulrichINJECT CT motion (K171392). The indications for use of the ulrichINJECT CT motion are equivalent to the indications for use of the previously cleared ulrichINJECT CT motion (K171392). The only difference is that the ulrichINJECT CT motion supports two additional contrast media, OMNIPAQUE single dose and VISIPAQUE single dose. This difference does not affect the intended use or safety and effectiveness of the device.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
	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. 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.	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 Components			
System	Injector Head Touch Terminal	Injector Head Touch Terminal	The system components of the ulrichINJECT CT motion are identical to the system components of the previously cleared ulrichINJECT CT motion (K171392).
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	The accessories of the ulrichINJECT CT motion are identical to the system components of the previously cleared ulrichINJECT CT motion (K171392).

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	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	The disposables of the ulrichINJECT CT motion are identical to the disposables of the previously cleared ulrichINJECT CT motion (K171392).
Physical Design			
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	The weight of the ulrichINJECT CT motion is identical to the weight of the previously cleared ulrichINJECT CT motion (K171392).
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	The dimensions of the ulrichINJECT CT motion are identical to the dimensions of the previously cleared ulrichINJECT CT motion (K171392).
Power Requirement Rated Voltage: Rated Current: Rated Frequency:	110 to 240 V AC 1.6 A 50/60Hz	110 to 240 V AC 1.6 A 50/60Hz	The power requirements of the ulrichINJECT CT motion are identical to the power requirements of the previously cleared ulrichINJECT CT motion (K171392).
Battery	Lead gel battery or Li-Ion battery	Lead gel battery	The battery of the ulrichINJECT CT motion is different from the previously cleared ulrichINJECT CT motion (K171392). This difference does not affect the intended use or safety or effectiveness of the device.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
Display Type	Color LCD Terminal with touch screen	Color LCD Terminal with touch screen	The display of the ulrichINJECT CT motion is identical to the display of the previously cleared ulrichINJECT CT motion (K171392).
Characteristics			
Syringeless system	Yes	Yes	ulrichINJECT CT motion is identical to the previously cleared ulrichINJECT CT motion (K171392). Both systems are syringeless.
Remote Operation	Yes, via the Touch Terminal	Yes, via the Touch Terminal	ulrichINJECT CT motion is identical to the previously cleared ulrichINJECT CT motion (K171392). Both systems provide remote operation.
Single Patient Use Disposable	Patient Tubing for Pump Tubing-flex	Patient Tubing for Pump Tubing-flex	The single patient use disposable of the ulrichINJECT CT motion is identical to the previously cleared ulrichINJECT CT motion (K171392).
Designed to Prevent Reuse of Disposables	Yes – via the use of software controls	Yes – via the use of software controls	ulrichINJECT CT motion is identical to the previously cleared ulrichINJECT CT motion (K171392). Both systems provide software controls to prevent user from reuse of disposables.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
Rotary peristaltic pump	Yes	Yes	The rotary peristaltic pump of the ulrichINJECT CT motion is identical to the rotary peristaltic pump of the previously cleared ulrichINJECT CT motion (K171392).
Used to administer contrast media and saline	Yes	Yes	ulrichINJECT CT motion is identical to the previously cleared ulrichINJECT CT motion. Both systems are used to administer contrast media and saline.
Disposable uses spikes to spike media container	Yes	Yes	ulrichINJECT CT motion is identical to the previously cleared ulrichINJECT CT motion. Both systems have disposables which use spikes to spike media containers.
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	The safety stop mechanism of the ulrichINJECT CT motion is identical to the safety stop mechanism of the previously cleared ulrichINJECT CT motion.
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	The volume remaining readout of the ulrichINJECT CT motion is identical to the volume remaining readout of the previously cleared ulrichINJECT CT motion.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
Programmable Pressure Limit	Yes, 195 PSI; user-programmable or automatic	Yes, 195 PSI; user-programmable or automatic	The programmable pressure limit of the ulrichINJECT CT motion is identical to the programmable pressure limit of the previously cleared ulrichINJECT CT motion.
Operational Characteristics			
Injection Capabilities	40 phases per protocol	40 phases per protocol	The injection capabilities of the ulrichINJECT CT motion are identical to the injection capabilities of the previously cleared ulrichINJECT CT motion.
Injection Rates for Contrast Media	0.1 mL/s to 10.0 mL/s	0.1 mL/s to 10.0 mL/s	The injection rates for contrast media of the ulrichINJECT CT motion are identical to the injection rates for contrast media of the previously cleared ulrichINJECT CT motion.
Injection Rates for Saline	0.1 mL/s to 10.0 mL/s	0.1 mL/s to 10.0 mL/s	The injection rates for saline of the ulrichINJECT CT motion are identical to the injection rates for saline of the previously cleared ulrichINJECT CT motion.
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	The injection volume per injection of the ulrichINJECT CT motion is identical to the injection volume per injection of the previously cleared ulrichINJECT CT motion.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
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%	The flow rate and volume accuracy of the ulrichINJECT CT motion is identical to the flow rate and volume accuracy of the previously cleared ulrichINJECT CT motion.
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)	The contrast media container volume of the ulrichINJECT CT motion is equivalent to the contrast media container volume of the previously cleared ulrichINJECT CT motion. The only difference is that the ulrichINJECT CT Motion includes an additional contrast media container volumes for Omnipaque and Visipaque. This difference has been addressed with the completion of a process simulation study.
Compatible Contrast Media	OMNIPAQUE™ IBP OMNIPAQUE™ single dose VISIPAQUE™ single dose	OMNIPAQUE™ IBP	The compatible contrast media of the ulrichINJECT CT motion is different from the compatible contrast media of the previously cleared ulrichINJECT CT motion.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
			This difference has been addressed with the completion of contamination control studies, extractable and leachable studies, and bench testing.
Saline Flush	Yes	Yes	The saline flush feature of the ulrichINJECT CT motion is identical to the saline flush feature of the previously cleared ulrichINJECT CT motion.
Needle Size	14-24 G	14-24 G	The needle size of the ulrichINJECT CT motion is identical to the needle size of the previously cleared ulrichINJECT CT motion.
Injection Pause	Programmable - 0 sec to 999 sec in 1 sec increments	Programmable - 0 sec to 999 sec in 1 sec increments	The injection pause of the ulrichINJECT CT motion is identical to the injection pause of the previously cleared ulrichINJECT CT motion.
Injection Protocol Storage	Yes	Yes	The injection protocol storage of the ulrichINJECT CT motion is identical to the injection protocol storage of the previously cleared ulrichINJECT CT motion.
Priming/Venting Rate	2 mL/s (manual)	2 mL/s (manual)	The priming/venting rate of the ulrichINJECT CT motion is identical to the priming/venting rate of the previously cleared ulrichINJECT CT motion.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
Air Detection Principle	Ultrasound	Ultrasound	The air detection principle of the ulrichINJECT CT motion is identical to the air detection principle of the previously cleared ulrichINJECT CT motion.
Technical Detection Limit of air in tubing	0.05 mL	0.05 mL	The technical detection limit of air in tubing of the ulrichINJECT CT motion is identical to the technical detection limit of air in tubing of the previously cleared ulrichINJECT CT motion.
Air Detector Alarm Limit	1 mL	1 mL	The air detector alarm limit of the ulrichINJECT CT motion is identical to the air detector alarm limit of the previously cleared ulrichINJECT CT motion.
Occlusion Detection Principle	Fail safe piezo-resistive pressure sensor	Fail safe piezo-resistive pressure sensor	The occlusion detection principle of the ulrichINJECT CT motion is identical to the occlusion detection principle of the previously cleared ulrichINJECT CT motion.
Occlusion Detection Alarm Limit	246 PSI	246 PSI	The occlusion detection alarm limit of the ulrichINJECT CT motion of the occlusion detection alarm limit of the previously cleared ulrichINJECT CT motion.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
Disposables			
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	The time limit for disposables of the ulrichINJECT CT motion is identical to the time limit for disposables of the previously cleared ulrichINJECT CT motion.
Package Sterile	Yes	Yes	The sterile packaging of the ulrichINJECT CT motion disposables is identical to the sterile packaging of the previously cleared ulrichINJECT CT motion.
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	The sterilization method of the ulrichINJECT CT motion is identical to the sterilization method of the previously cleared ulrichINJECT CT motion.
Packaging Configuration	Tyvek lid covering polystyrele tray	Tyvek lid covering polystyrele tray	The packaging configuration of the ulrichINJECT CT motion is identical to the sterilization method of the previously cleared ulrichINJECT CT motion.
Patient Tubing			

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
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	The patient tubing components of the ulrichINJECT CT motion are identical to the patient tubing components of the previously cleared ulrichINJECT CT motion.
Safety Feature Against Re-use	Yes, via software controls	Yes, via software controls	The safety features to protect against reuse of patient tubing for the ulrichINJECT CT motion are identical to the safety features to protect against reuse of patient tubing for the previously cleared ulrichINJECT CT motion.
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	The pump-tubing flex components of the ulrichINJECT CT motion are identical to the pump-tubing flex components of the previously cleared ulrichINJECT CT motion.
Contrast Media Line Tubing Material	PVC / PUR	PVC / PUR	The pump tubing-flex contrast media line tubing material of the ulrichINJECT CT motion is identical to the pump tubing-flex contrast media line tubing material of the previously cleared ulrichINJECT CT motion.

Characteristic	ulrichINJECT CT motion *(Subject Device)*	ulrichINJECT CT motion (K171392) *(Primary Predicate)*	Comparison
Saline Line Tubing Material	PVC / PUR	PVC / PUR	The pump tubing-flex saline line tubing material of the ulrichINJECT CT motion is identical to the pump tubing-flex saline line tubing material of the previously cleared ulrichINJECT CT motion.
Spike for CT			
Spike Size	28.5 mm	28.5 mm	The spike size of the ulrichINJECT CT motion is identical to the spike size of the previously cleared ulrichINJECT CT motion.
Safety Feature Against Re-Use	Yes, via software controls	Yes, via software controls	The safety feature against re-use of spikes for the ulrichINJECT CT motion is identical to the safety feature against re-use of spikes for the previously cleared ulrichINJECT CT motion.

In conclusion, the intended use for ulrichINJECT CT motion is the same as that of the previously cleared ulrichINJECT CT motion (K171392). The technological characteristics demonstrate that the ulrichINJECT CT motion is equivalent to previously cleared ulrichINJECT CT motion (K171392), and the testing shows that the ulrichINJECT CT motion is substantially equivalent to the previously cleared ulrichINJECT CT motion (K171392) and assures that the ulrichINJECT CT motion is as safe and effective as the previously cleared ulrichINJECT CT motion (K171392).

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 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 an installation qualification and an operational / performance qualification. The ulrichINJECT CT motion software is unconditionally accepted. All acceptance criteria for the Installation Qualification and Operational and Performance Qualification are satisfactorily met so that the Software is released for its intended use.

Electromagnetic Compatibility / Electrical Safety

Testing was performed in accordance with the following standards as part of K171392:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Additional EMC Testing has been performed to demonstrate conformance to IEC 60601-1-2 4th edition.

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:

- 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 accelerating aging studies were performed as part of K171392. Additional real time aging shelf-life data is also provided for this submission. 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.

Chemical Compatibility
Material compatibility of the ulrichINJECT CT motion tubing system was performed 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 has performed the following contamination control studies:

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

Contamination control study results has 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:

- 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
- Pyrogens

- 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 for OMNIPAQUE. This testing was repeated for VISIPAQUE for this submission.

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.

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.

Although the components of ulrichINJECT CT motion system have not changed since K171392, additional verification testing has been performed to further 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, K171392.