November 9, 2017

ulrich GmbH & Co. KG
% Rita King
CEO
MethodSense, Inc.
PO Box 110352
Durham, North Carolina 27709

Re: K171392
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: October 3, 2017
Received: October 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K171392

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).

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K171392

510(k) Summary

ulrich GmbH & Co. KG

This 510(k) Summary is in conformance with 21 CFR 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: November 7, 2017

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:

Trade Name:	CT Exprès 3D Contrast Media Delivery System
Common Name:	Automatic injector for contrast media
510(k) Submitter / Holder	Bracco Injeneering S.A.
510(k) Number	K151048
Classification:	Class II
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.

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 only component of the ulrichINJECT CT motion that comes in contact with the patient is the ulrichINJECT CT motion tubing system. The tubing system consists of three components:

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

The ulrichINJECT CT motion tubing system has indirect contact with the blood path of a patient for a limited duration (few minutes)**.**

The ulrichINJECT CT motion system is also intended to be used with the following components, which are not supplied with the system:

- Multiple patient use saline containers,
- Omnipaque™ IBP contrast media containers, and
- Cannula.

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).

ulrichINJECT CT motion is equipped with multiple hardware and software controls that work together for 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 it is designed to operate with a rechargeable 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).

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.

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 device in the CT suite and evaluated risks related to safety, contamination and usability. 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, adverse tissue reaction, infection and improper use.

Substantial Equivalence
ulrichINJECT CT motion is substantially equivalent to CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A., (K151048) currently on the market.

ulrichINJECT CT motion has the same indications for use as the Bracco Injeneering CT Expres 3D Contrast Media Delivery System and uses equivalent overall design and operating principals.

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

Detailed Comparison of the Subject and Predicate Device

Product Name:	**ulrichINJECT CT motion by ulrich Medical**	**CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048**	**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). 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	The CT Expres 3D Contrast Media Delivery System is indicated for controlled automatic administration, on the venous side, of contrast and saline, to human subjects while undergoing examination by means of a computed tomography (CT) scanner. The CT Expres 3D Contrast Media Delivery System is specifically indicated for use in CT procedures for the delivery of Isovue (Iopamidol Injection) contrast media as supplied in Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media or a maximum of ten (10) hours, whichever comes first, per Day Set III HP disposable. The Bottle Spike disposable is for single-bottle use only and must be discarded with the contrast media bottle. The Patient Set disposable must be discarded after each	ulrichINJECT CT motion is equivalent to CT Expres 3D. The differences in the time limits of the disposables components are addressed through the results of contamination control studies.

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
	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.	patient procedure. The CT Expres 3D is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.	
System Components			
System	Injector Head Touch Terminal	CT Expres Injector Unit CT Expres Control Panel	ulrichINJECT CT motion is equivalent to CT Expres 3D.
Accessories	Injector Base Wall Mount with moveable arm Ceiling Mount with moveable arm Contrast Media Housing with Heater	CT Expres Hand Switch CT Expres Bottle Insulator CT Expres Stand CT Expres Ceiling mount	ulrichINJECT CT motion Pedestal, Ceiling Mount and Contrast Media Housing with Heater are equivalent to the CT Expres 3D Stand.

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
			ulrichINJECT CT motion does not include a hand switch.
Disposables	ulrichINJECT CT Motion Pump Tubing-flex Patient Tubing for Pump Tubing-flex ulrichINJECT CT Motion Spike for CT	CT Expres Day Set III HP CT Expres Patient Set CT Express Bottle Spike Type B (25mm)	ulrichINJECT CT motion disposables are equivalent to the CT Expres 3D disposables.
Physical Design			
Weight	Injector: Approx. 79 kg Terminal: Approx. 3 kg	Injector: Approx. 10 kg Remote Control Panel: Approx. 2.1 kg	ulrichINJECT CT motion weight is equivalent to the CT Expres 3D weight. ulrichINJECT CT motion Injector is heavier than the CT Express 3D injector. However, this difference does not have an impact on the intended use of the device.
Dimensions	Injector: 64.5 x 64.5 x 144.5 cm Terminal: 31 x 27.5 x 17 cm	Injector: 44 x 32 x 16 cm Remote Control Panel: 30 x 20 x 22 cm	ulrichINJECT CT motion dimensions are equivalent to the CT Expres 3D dimensions.
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	ulrichINJECT CT is identical to the CT Expres 3D related to power requirements.

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
Display Type	Color LCD Terminal with touch screen	Color LCD with touch screen	ulrichINJECT CT motion Terminal is equivalent to the CT Expres 3D Console.
Characteristics			
Syringeless system	Yes	Yes	CT motion is identical to CT Express 3D
Remote Operation	Yes, via the Touch Terminal	Yes, via the Remote Control Panel and the Hand Switch	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to remote operation.
Single Patient Use Disposable	Patient Tubing for Pump Tubing-flex	Patient Set	ulrichINJECT CT motion Patient Tubing for Pump Tubing-flex is equivalent to the CT Expres 3D Patient Set. CT Expres 3D Patient Set includes the peristaltic pump into the disposable. The peristaltic pump is part of the injector of the ulrichINJECT CT motion. This difference in technology does not affect the intended use of the device.
Designed to Prevent Reuse of Disposables	Yes – via the use of software controls	Yes – via a breakaway pin designed to break on insertion	ulrichINJECT CT motion is equivalent to the CT Expres 3D. ulrichINJECT CT motion provides software controls to

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
			prevent user from reuse of disposables.
Rotary peristaltic pump	Yes	Yes	CT motion is equivalent to CT Express 3D
Used to administer contrast media and saline	Yes	Yes	CT motion is equivalent to CT Express 3D
Disposable uses spikes to spike media container	Yes	Yes	CT motion is equivalent to CT Express 3D
Safety Stop Mechanism	Multi-layered software stops; Used Patient Tubing detector and Pump Tubing-flex detector	Multi-layered software stops; Used Pump Tubing detector	CT motion is equivalent to CT Express 3D
Volume Remaining Readout	Yes, displayed on control unit if programmed volume is higher than remaining volume	Yes, LED on injector head; graphical and numeric on LCD	CT motion is equivalent to CT Express 3D
Programmable Pressure Limit	Yes, 195 PSI; user-programmable or automatic	Yes, 8 bar (ca. 120 psi)	CT motion is equivalent to CT Express 3D
Operational Characteristics			

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
Injection Capabilities	40 phases per protocol	Up to 24 phases per patient (8 phases per injection; up to 3 injections per patient)	ulrichINJECT CT motion is equivalent to the CT Expres 3D. ulrichINJECT CT motion provides additional flexibility with a greater number of phases for programming different speed and volume of contrast media and saline for better imaging quality.
Injection Rates for Contrast Media	0.1 ml/s to 10.0 ml/s	0.5-9.9 mL/s	ulrichINJECT CT motion is equivalent to the CT Expres 3D.
Injection Rates for Saline	0.1 ml/s to 10.0 ml/s	0.1-9.9 mL/s	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to the injection rates for saline.
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	10-200 mL/s with a max of 400 mL total media (contrast and saline) per patient	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to injection volume per injection.
Flow Rate and Volume Accuracy	10-200 mL of contrast media with volume accuracy of $\pm$ 5% Flow rate accuracy of $\pm$ 5%	+/- 10% for a programmed injection volume between 10 mL and 59 mL +/- 6% for a programmed injection volume between 60 mL and 200 mL	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to flow rate and volume accuracy with a greater flow rate accuracy delivered by ulrichINJECT CT motion.

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
Contrast Media Container Volume	500 mL	200 & 500 mL	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to contrast media container volume.
Saline Flush	Yes	Yes	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to saline flush.
Needle Size	14-24 G	16-24 G	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to needle sizes
Injection Pause	Programmable - 0 sec to 999 sec in 1 sec increments	0-400 seconds	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to injection pause
Injection Protocol Storage	Yes	Yes	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to injection protocol storage
Priming/Venting Rate	2 mL/s (manual)	1.5 mL/s (manual) 6.0 mL/s (automatic)	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to priming/venting rate

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
Air Detection Principle	Ultrasound	Ultrasound	ulrichINJECT CT motion is identical to the CT Expres 3D related to air detection principle
Technical Detection Limit of air in tubing	0.05 mL	0.04 mL	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to technical detection limit of air in tubing.
Air Detector Alarm Limit	1 mL	For programmed injection volume < or equal to 35 mL CM, 1.25 mL For programmed injection volume > or equal to 35 mL CM, 1.25 mL if fragment air bubble, otherwise an additional air volume of 0.75 mL is tolerated. Note: The volume of the Patient Set (after the air detector) is 8 mL	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to air detection alarm limit.
Occlusion Detection Principle	Fail safe piezo-resistive pressure sensor	Fail safe piezo-resistive pressure sensor	ulrichINJECT CT motion is identical to the CT Expres 3D related to occlusion detection principle.

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
Occlusion Detection Alarm Limit	246 PSI	132 PSI	ulrichINJECT CT motion is equivalent to the CT Expres 3D related to occlusion detection alarm limit.
Disposables			
Time Limit	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	12 hours for CT Expres Day Set III HP 3 hours for CT Expres Patient Set 10 hours for CT Express Bottle Spike Type B (25mm)	ulrichINJECT CT motion is equivalent to CT Expres 3D. The differences in time limits between the ulrichINJECT CT motion and the predicate device are addressed with the completion of contamination control studies.
Package Sterile	Yes	Yes	ulrichINJECT CT motion is identical to CT Expres 3D.
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	ulrichINJECT CT motion is identical to CT Expres 3D.
Packaging Configuration	Tyvek lid covering polystyrele tray	Tyvek lid covering polystyrele tray	ulrichINJECT CT motion is equivalent to CT Expres 3D.
Patient Tubing			

Product Name:	**ulrichINJECT CT motion by ulrich Medical**	**CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048**	**Comparison**
Components	Patient Tubing Two Patient Luer Connectors with safety caps Two check valves	Patient Set Cassette Patient Set Tubing Pinch Clamp Patient Connector with Safety Cap	ulrichINJECT CT motion is equivalent to the CT Expres 3D. ulrichINJECT CT motion peristaltic pump is part of the injector.
Safety Feature Against Re-use	Yes, via software controls	Break away pin designed to break on insertion	ulrichINJECT CT motion is equivalent to the CT Expres 3D. ulrichINJECT CT motion provides software controls that includes notifications to the user that disposables have expired and requires user action in order for the system to continue.
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	T-connector Contrast media line x2 Spike for saline line Saline line Filter x2 Reservoir x2 Tubing guide x2	ulrichINJECT CT motion is equivalent to the CT Expres 3D Day Set III HP.
Contrast Media Line Tubing Material	PVC / PUR	PVC tubing	ulrichINJECT CT motion is equivalent to the CT Expres 3D.

Product Name:	ulrichINJECT CT motion by ulrich Medical	CT Expres 3D Contrast Media Delivery System by Bracco Injeneering S.A. K151048	Comparison
Saline Line Tubing Material	PVC / PUR	PVC tubing	ulrichINJECT CT motion is equivalent to the CT Expres 3D.
Spike for CT			
Spike Size	28.5 mm	25 mm	ulrichINJECT CT motion is equivalent to the CT Expres 3D.
Safety Feature Against Re-Use	Yes, via software controls	Spike tip designed to break off into bottle on removal	ulrichINJECT CT motion is equivalent to the CT Expres 3D. ulrichINJECT CT motion provides software controls that includes notifications to the user that disposables have expired and requires user action in order for the system to continue.

Summary of the nonclinical testing as a basis for Substantial Equivalence
ulrichINJECT CT motion system and software were validated in accordance with a Verification & Validation plan to ensure conformance with established performance criteria.

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
- 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 testing performed is listed below.

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:
ulrich performed real time aging and accelerating aging studies. The ulrichINJECT CT motion tubing system is sterilized and its packaging was validated in accordance with ISO 11607-1: 2006 Packaging for terminally sterilized medical devices - Part 1: requirements for materials, sterile barrier systems and packaging systems.

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

Chemical Compatibility
The only component of the ulrichINJECT CT motion that comes in contact with the patient is the ulrichINJECT CT motion tubing system. To support the material compatibility of the ulrichINJECT CT motion tubing system with Omnipaque™ Imaging Bulk Package (IBP), material compatibility testing was performed using Omnipaque™ 350 mgI/ml as the solvent. The results concluded that the ulrichINJECT CT motion tubing system does not interact with Omnipaque™ and the chemical integrity of Omnipaque™ is not compromised throughout use.

Contamination Control:
Ulrich performed three contamination control studies:

- Process simulation study
- Microbial ingress study
- Cross contamination study

Based on these results, it has been 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) during its intended use.

Biocompatibility:
The ulrichINJECT CT motion tubing system indirect patient contact materials were verified in accordance with the following standard:

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

Verification results indicated that the materials comply with the standard.

Performance – Bench:
The ulrichINJECT CT motion tubing system was tested for performance and verified in accordance with the following standards:

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

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

Additional performance bench testing included testing using each disposable component of the ulrichINJECT CT motion tubing system to evaluate the device pressure when using the device with multiple size cannulas at multiple flow rates and to demonstrate that the device is capable of delivering contrast media and saline at the prescribed rate and total volume for the expected range of cannulas.

Additional testing included extractables and simulation testing for leachable compounds and particulates. Transport validation and cleaning instructions validation was performed.

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

Summary of the clinical testing as a basis for Substantial Equivalence
No clinical studies were performed using ulrichINJECT CT motion. Human Factors / Usability assessments were performed in a simulated use environment. The results demonstrated that users can operate ulrichINJECT CT motion as the predicate device.

Substantial Equivalence Conclusions

In conclusion, the indications for use for the ulrichINJECT CT motion are substantially equivalent to that of the predicate device. The technological characteristics comparison demonstrates that the ulrichINJECT CT motion is equivalent to the predicate device, and the testing shows that the ulrich ulrichINJECT CT motion is substantially equivalent to the predicate device.

Conclusion

The 510(k) Pre-market Notification for the ulrichINJECT CT motion contains adequate information and data to determine that ulrichINJECT CT motion is substantially equivalent to the legally marketed predicate device.