December 21, 2016

ulrich GmbH & Co. KG

Re: K161723

Trade/Device Name: ulrich Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Sets
Regulatory Class: II
Product Code: PQH
Dated: December 16, 2016
Received: December 19, 2016

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
### Indications for Use

**510(k) Number (if known)**  
K161723

**Device Name**  
ulrich Transfer Set

**Indications for Use (Describe)**  
The ulrich Transfer Set is indicated for the transfer of OmnipaqueTM (Iohexol) contrast media as supplied in an Imaging Bulk Package to non pre-filled single-use only sterile syringes on syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side of contrast media for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 8 hours have elapsed since the container was penetrated, whichever occurs first.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) Summary

**ulrich GmbH & Co. KG K161723**

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:** December 20 2016

## Device Name and Classification

| **Trade Name:** | ulrich Transfer Set  
| **Common Name:** | Iodinated Contrast Media Transfer Set |
| **Classification:** | Class II |
| **Regulation Number/Name:** | 21 CFR 880.5440, Intravascular Administration Set  
| **Classification Panel:** | General Hospital Devices Branch (GHDB)  
| **Product Code:** | PQH |

**Predicate Device:**

| **Trade Name:** | Bracco Injeneering Transfer Set  
| **Common Name:** | Intravascular Administration Set  
| **510(k) Submitter / Holder:** | Bracco Injeneering S.A.  
| **510(k) Number:** | K133147  
| **Classification:** | Class II  
| **Regulation Number:** | 21 CFR 880.5440, Intravascular Administration Set  
| **Classification Panel:** | General Hospital  
| **Product Code:** | FPK |

**Reference Device:**

| **Trade Name:** | Swabsite Swabbable Valve  
| **Common Name:** | Intravascular Administration Set Swabbable Valve  
| **510(k) Submitter / Holder:** | QUEST MEDICAL, INC  
| **510(k) Number:** | K002689  
| **Classification:** | Class II |
**Device Description and Intended Use**

The ulrich Transfer Set (Transfer Set) is a sterile tubing set connection between an imaging bulk package and empty sterile syringes on single-use-only, syringe based contrast injection systems. The Transfer Set consists of a spike with protective cap and integrated air filter on one side, 20" (50.8 cm) tubing segment and one female swabbable (also referenced as swabbable) valve (Swabsite Swabbable Valve - K002689) with a protective cap on the other side. The Transfer Set is to be discarded after the contrast media container has been depleted or 8 hours have elapsed since the container was penetrated, whichever occurs first.

The Transfer Set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe based contrast injector systems.

**Indications for Use**

The ulrich Transfer Set is indicated for the transfer of Omnipaque™ (Iohexol) contrast media as supplied in an Imaging Bulk Package to non pre-filled single-use only sterile syringes on syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side of contrast media for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 8 hours have elapsed since the container was penetrated, whichever occurs first.

**Risk Analysis Method**

The ulrich Transfer Set was assessed to determine the risks to health associated with the use of intravascular administration sets and accessories. A risk analysis was conducted in accordance with ISO 14971:2012, 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**

The ulrich Transfer Set is substantially equivalent to the Bracco Injeneering Transfer Set (K133147) predicate device currently on the market.

ulrich Transfer Set has the same intended use as the Bracco Injeneering Transfer Set. The ulrich Transfer Set has substantially equivalent indications for use with the Bracco Injeneering Transfer Set. Ulrich transfer set is indicated for the transfer of Omnipaque™ (Iohexol) contrast media as supplied in an Imaging Bulk Package while the Bracco Injeneering Transfer Set is indicated for the transfer of Isovue (lopamidol Injection) contrast media as supplied in an Imaging Bulk Package. ulrich Transfer Set uses equivalent overall design and operating principals to Bracco Injeneering Transfer Set.

The table below provides a detailed comparison of ulrich Transfer Set to the predicate device.

**Detailed Comparison of the Subject and Predicate Device**
<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>The transfer set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe-based contrast injection systems.</td>
<td>The transfer set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe based contrast delivery systems (injectors).</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The ulrich Transfer Set is indicated for the transfer of Omnipaque™ (Iohexol) contrast media as supplied in an Imaging Bulk Package to non pre-filled single-use only sterile syringes on syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side of contrast media for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 8 hours have elapsed since the container was penetrated, whichever occurs first.</td>
<td>The Bracco Injeneering Transfer Set is a component of a contrast management system and is indicated for the transfer of Isovue (lopamidol Injection) contrast media as supplied in an Imaging Bulk Package to empty sterile syringes on single-use only syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side, of contrast agents for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 10 hours has elapsed since the container was penetrated, whichever occurs first.</td>
<td>Substantially equivalent to the Predicate device.</td>
</tr>
<tr>
<td>Tubing Length</td>
<td>20”</td>
<td>20”</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Biocompatible</td>
<td>Yes</td>
<td>Yes</td>
<td>Substantially equivalent to the Predicate device.</td>
</tr>
<tr>
<td>Sterile</td>
<td>Yes</td>
<td>Yes</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Sterility Assurance Level</td>
<td>10⁶</td>
<td>10⁶</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Item</td>
<td>Subject Device</td>
<td>Predicate Device</td>
<td>Comparison</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Ethylene Oxide (EtO)</td>
<td>Ethylene Oxide (EtO)</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Disposable</td>
<td>Yes</td>
<td>Yes</td>
<td>Substantially equivalent to the Predicate device.</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>one (1) year shelf life</td>
<td>one (1) year shelf life</td>
<td>Identical to the Predicate device.</td>
</tr>
<tr>
<td>Packaging</td>
<td>Individually packaged in a Tyvek pouch</td>
<td>Individually packaged in a Tyvek pouch</td>
<td>Substantially equivalent to the Predicate device.</td>
</tr>
<tr>
<td>Microbial Ingress Testing</td>
<td>Yes</td>
<td>Yes</td>
<td>Substantially equivalent to the Predicate device.</td>
</tr>
<tr>
<td>Chemical Compatibility Testing</td>
<td>Yes</td>
<td>Yes</td>
<td>Substantially equivalent to the Predicate device.</td>
</tr>
<tr>
<td>Protective Cap for swabable valve</td>
<td>Yes</td>
<td>No</td>
<td>The ulrich Transfer Set provides a protective cap for the swabbable valve.</td>
</tr>
</tbody>
</table>
Reference Device

The ulrich Transfer Set uses a female swabable valve, Swabsite Swabbable Valve Application (K002689) by QUEST MEDICAL, INC without any changes to the valve. Halkey-Roberts Corporation is the current legal manufacturer of the Swabsite Swabbable Valve while QUEST MEDICAL, INC is the 510(k) Submitter.

Testing

Sterilization:

The ulrich Transfer Set 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:


Verification results indicate that the ulrich Transfer Set complies with the standard.

Shelf-Life:

The ulrich Transfer Set is sterilized and its packaging was validated in accordance with the following standards:

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

Verification results indicate that the ulrich Transfer Set complies with the standards.

Biocompatibility:

The ulrich Transfer Set indirect patient contact materials were verified in accordance with the following standards:

- ISO 10993-4: 2009 Biological evaluation of medical devices Part 4: Selections of tests for interactions with blood
- ISO 10993-10: 2010 Biological evaluation of medical devices Part 10: Tests for Irritation and Skin Sensitization
- ASTM F756-13 Standard Practice for Assessment of Haemolytic Properties Materials
- ASTM F619-14 Standard Practice for Extraction of Medical Plastics
• USP 38 <151> Pyrogen Test, 38-NF33:2015
• USP 38 <85> 2015 Bacterial Endotoxins Test
• USP 38 <161> 2014 Transfusion and infusion assemblies and similar medical devices

Verification results indicated that the materials comply with the standards.

Performance – Bench:

The ulrich Transfer Set 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
• ISO 22413:2010, Transfer sets for pharmaceutical preparations -- Requirements and test methods
• ISO 594-2, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings (Swabsite Swabbable Valve, K002689)

Additional testing included:

• Microbial ingress testing;
• Chemical compatibility – Through evaluation of conformance to the approved release specification of Omnipaque.
• Extractables and simulation testing for leachable compounds and particulates.

Test and verification results indicate that the ulrich Transfer Set complies with its predetermined specifications and the applicable standards.

Substantial Equivalence Conclusion
In conclusion, the intended use for the ulrich Transfer Set is the same as that of the predicate device. The technological characteristics comparison and testing demonstrates that the ulrich Transfer Set is substantially equivalent to predicate device.