



November 18, 2020

Liebel-Flarsheim Company LLC
% Matthew Helmi
Regulatory Affairs Associate II
Guerbet LLC
821 Alexander Road Suite 204
Princeton, New Jersey 08540

Re: K193010

Trade/Device Name: Liebel-Flarsheim™ IBP Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: PQH
Dated: November 16, 2020
Received: November 17, 2020

Dear Matthew Helmi:

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/pmnmn.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 Payal Patel

Acting 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

Indications for Use

510(k) Number (if known)

K193010

Device Name

Liebel-Flarsheim™ IBP Transfer Set

Indications for Use (Describe)

The Liebel-Flarsheim™ IBP Transfer Set is indicated for the transfer of Optiray® (Ioversol) Imaging Bulk Package contrast media to empty, single-use only, sterile syringes on syringe based contrast injection systems indicated for the controlled, automatic intra-vascular administration of radiopaque contrast agents for their indicated procedures. The IBP Transfer Set is to be discarded after the contrast media container has been emptied or after 12 hours have elapsed since the container was penetrated, whichever occurs first.

Contra-indications for the use of this device are determined by the prescribing physician at the time of use based upon the contrast media package inserts.

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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**Traditional Premarket Notification
Submission – 510(k) Summary
Liebel-Flarsheim™ IBP Transfer Set
K193010**

Submitter

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Date: November 16, 2020

Device Name and Classification

Trade Name: Liebel-Flarsheim™ IBP Transfer Set
Common Name: Iodinated Contrast Media Transfer Tubing
Set Classification: Class II
Regulation: 21 CFR 880.5440, Intravascular Administration
Set. Review Panel: General Hospital
Product Code: PQH (Iodinated Contrast Media Transfer Tubing Set)

Predicate Device

Trade Name: ulrich Transfer Set
K Number: K161723
Common Name: Iodinated Contrast Media Transfer
Set Classification: Class II
Regulation: 21 CFR 880.5440, Intravascular Administration
Set. Review Panel: General Hospital
Product Code: PQH (Iodinated Contrast Media Transfer Tubing Set)

5.1. Device Information

Device Description and Intended Use

The Liebel-Flarsheim™ IBP Transfer Set is a sterile tubing set connection between Optiray® (Ioversol) contrast media imaging bulk packages (hereinafter Optiray IBPs) and empty sterile single-use syringes on syringe-based automatic contrast injection systems. The Liebel-Flarsheim™ IBP Transfer Set consists of a small bore (1/8" ID) clear polyvinyl chloride (PVC) tube with standard medical component end terminations. Bonded to the proximal end of the PVC tube is a vented IV spike that is used to pierce a rubber stopper belonging to an imaging bulk contrast media container. Distally, a self-sealing Luer type connector (Smiths Medical Nu- Site®) is bonded to the opposite end of the PVC tube. The Liebel-Flarsheim™ IBP Transfer Set, shown in the image below, has an overall length of 19-inches, a protective cap on the IV Spike, and both untethered and tethered protective caps on the Luer end to protect the Nu-Site® Luer Activated fitting between syringe fills. The transfer sets are individually packaged in blister packs with a perimeter heat sealed Tyvek lid. Sealed blister packs are packaged in an outer box containing 50 units (50 units/box) which are terminally sterilized with ethylene oxide.

The Liebel-Flarsheim™ IBP Transfer Set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe-based contrast injection systems.

Image 1: Liebel-Flarsheim™ IBP Transfer Set



Indications for Use

The Liebel-Flarsheim™ IBP Transfer Set is indicated for the transfer of Optiray® (Ioversol) Imaging Bulk Package contrast media to empty, single-use only, sterile syringes on syringe based contrast injection systems indicated for the controlled, automatic intra-vascular administration of radiopaque contrast agents for their indicated procedures. The IBP Transfer Set is to be discarded after the contrast media container has been emptied or after 12 hours have elapsed since the container was penetrated, whichever occurs first.

Contra-indications for the use of this device are determined by the prescribing physician at the time of use based upon the contrast media package inserts.

Risk Analysis Method

The Liebel-Flarsheim™ IBP Transfer Set was assessed for risks to health associated with the use of intravascular administration sets and accessories. Risks including but not limited to device malfunctions, bio-incompatibility risks, infection risks, and improper use were assessed. This device risk analysis was conducted in accordance with ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices.

5.2. Substantial Equivalence

The Liebel-Flarsheim™ IBP Transfer Set is substantially equivalent to the ulrich Transfer Set (K161723) predicate device, currently legally marketed in the United States of America. The Liebel-Flarsheim™ IBP Transfer Set has the same intended use and substantially equivalent indications for use as the ulrich Transfer Set. The Liebel-Flarsheim™ IBP Transfer Set is indicated for the transfer of Optiray® (Ioversol) Imaging Bulk Package contrast media while the ulrich Transfer Set is indicated for the transfer of Omnipaque™ (Iohexol) Imaging Bulk Package contrast media. The Liebel-Flarsheim™ IBP Transfer Set uses equivalent overall design and operating principals to the ulrich Transfer Set. The materials of the components are comparable to the predicates.

Similar tests and test methods performed in accordance with the same standards were used with the transfer set and the predicate device to validate the design. Safety questions have been evaluated for the transfer set through extensive design verification and validation testing. The above described differences do not adversely affect the safety or effectiveness of the transfer set as compared to the predicate device for the following reasons:

- a. **Biocompatibility:** An evaluation of biocompatibility was performed in compliance with ISO 10993-1:2018.
- b. **Performance Testing (Bench):** Bench testing, including but not limited to functional testing, chemical compatibility, and microbial ingress testing, was performed to verify the device for its intended use. The acceptance criteria were chosen to ensure that the device performs in an equivalent than the predicate device.

5.2.1 Summary Comparison of Subject and Predicate Device

Table 1: Comparison of Subject and Predicate Device

Item	Subject Device Liebel-Flarsheim™ IBP Transfer Set K193010	Predicate Device ulrich Transfer Set K161723	Comparison
Intended Use	The Liebel-Flarsheim™ IBP Transfer Set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe-based contrast injection systems.	The transfer set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe based contrast delivery systems (injectors).	Identical to the predicate device.
Indications for Use	<p>The Liebel-Flarsheim™ IBP Transfer Set is indicated for the transfer of Optiray® (Ioversol) Imaging Bulk Package contrast media to empty, single-use only, sterile syringes on syringe based contrast injection systems indicated for the controlled, automatic intra-vascular administration of radiopaque contrast agents for their indicated procedures. The IBP Transfer Set is to be discarded after the contrast media container has been emptied or after 12 hours have elapsed since the container was penetrated, whichever occurs first.</p> <p>Contra-indications for the use of this device are determined by the prescribing physician at the time of use based upon the contrast media package inserts.</p>	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.	Substantially equivalent to the predicate device.

Item	Subject Device Liebel-Flarsheim™ IBP Transfer Set K193010	Predicate Device Ulrich Transfer Set K161723	Comparison
Tubing Length	19 inches	20 inches	Substantially equivalent to the predicate device. Does not impact performance
Single Use	Yes	Yes	Identical to the predicate device.
Biocompatible	Yes - ISO 10993-1	Yes - ISO 10993-1	Substantially equivalent to the predicate device.
Sterile	Yes	Yes	Identical to the predicate device.
Sterility Assurance Level	10 ⁻⁶	10 ⁻⁶	Identical to the predicate device.
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Identical to the predicate device.
Shelf Life	Three (3) year shelf life.	One (1) year shelf life.	Substantially equivalent to the predicate device. Shelf life testing has been completed and demonstrated that the differences do not raise new questions of safety and effectiveness.

Item	Subject Device Liebel-Flarsheim™ IBP Transfer Set K193010	Predicate Device Ulrich Transfer Set K161723	Comparison
Packaging	Individually packaged in a Tyvek pouch.	Individually packaged in a Tyvek pouch.	Substantially equivalent to the predicate device.
Microbial Ingress Testing	Yes	Yes	Substantially equivalent to the predicate device.
Chemical Compatibility Testing	Yes - Optiray® (Ioversol) Imaging Bulk Package	Yes - Omnipaque™ (Iohexol) Contrast Media	Substantially equivalent to the predicate device.
Design- Protective Cap for Luer Connection	Yes - Tethered Cap with Smiths Medical Nu-Site® Luer Actuated Connector	Yes - With Halkey-Roberts Swabbable Valve	Substantially equivalent to the predicate device.
Design- Spike	Protected IV Spike with Vent	Spike with Protected Cap and Integrated Air Filter	Substantially equivalent to the predicate.
Use Life (After puncturing IBP)	12 Hours or disconnection from IBP (whichever occurs first)	8 Hours or disconnection from IBP (whichever occurs first)	Substantially equivalent to the predicate.
Material Differences	<u>Fluid Contacting Tubing</u> Non DEHP PVC <u>Spike</u> ABS <u>Luer</u> Polyurethane Hosing Silicone Seal Acetal Actuator	Unknown	Substantially equivalent to the predicate.

5.2.2 Summary of substantial equivalence discussion

In summary, the subject device's principle of operation, intended use, functional performance, and similar technological characteristics are substantially equivalent to those of the predicate device. Any differences in characteristics between the subject device and predicate device do not raise questions of safety or effectiveness. The subject device is substantially equivalent to the legally marketed predicate device.

5.3 Testing

5.3.1 Sterilization

The Liebel-Flarsheim™ IBP Transfer Set is ethylene oxide (EtO) sterilized and was validated to a sterility assurance level (SAL) of 10^{-6} in accordance with the following standards:

- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

EtO residuals are tested to ISO 10993-7:2008 limits. Validation results indicate that the Liebel-Flarsheim™ IBP Transfer Set complies with the standards.

5.3.2 Shelf Life

The proposed labeled shelf life of the Liebel-Flarsheim™ IBP Transfer Set is three years. Verification and validation testing in accordance with the framework described in (but not in full conformity with) ISO 11607 has been conducted, validated the process, and verified that the primary package (sterile barrier) maintains its integrity throughout the course of the labeled three year shelf life as further described in Section 12 – *Sterilization and Shelf Life*. Maintenance of functional user requirements over the proposed three year shelf life was also verified as described in Section 16 – *Performance Testing – Bench*.

5.3.3 Biocompatibility

The Liebel-Flarsheim™ IBP Transfer Set indirect patient contact materials were verified in accordance with the following standards:

- ISO 10993-1:2018 Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.
 - Cytotoxicity
 - Hemocompatibility
 - Irritation
 - Sensitization
 - Acute Systemic Toxicity
 - Material Mediated Pyrogenicity Test

- ISO 10993-18:2005 Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials Within a Risk Management Process
- USP <788> Particulate Matter in Injections
- USP <85> Bacterial Endotoxin Test

Verification results indicate that the materials comply with the standards.

5.3.4 Performance – Bench

The Liebel-Flarsheim™ IBP 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 594-2, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings.
- ISO 22413:2010, Transfer sets for pharmaceutical preparations -- Requirements and test methods.

Additional testing included:

- Microbial Ingress Testing
- Chemical Compatibility through Approved Release Specifications for Optiray® (Ioversol) Imaging Bulk Package
- Extractables and simulation testing for leachable compounds and particulates
- Verification of functional performance according to product specifications

5.4 Conclusions

The transfer set has the same intended use as the predicate device, differing only in the claimed compatible contrast media and access duration. The principle features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate devices do not raise any new questions of safety or effectiveness. Performance data, including Bench Testing and Biocompatibility, have established that the transfer set performs as intended. The subject device is substantially equivalent to the legally marketed predicate device.