June 7, 2018

International Medical Industries Inc.  
Kathleen Lavender  
Director of Quality and Compliance  
2981 Gateway Drive  
Pompano Beach, Florida 33069  

Re: K173577  
Trade/Device Name: Guarded Luer Connector  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: Class II  
Product Code: LHI  
Dated: May 8, 2018  
Received: May 10, 2018

Dear Kathleen Lavender:

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 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,

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

(Describe)
The Guarded Luer Connector is a fluid transfer device used in the pharmacy to provide the fluid path for transferring large source container ingredients into a smaller container.

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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PRASstaff@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."
**K173577 510(k) Summary**

**Company:** International Medical Industries, Inc.  
**Address:** 2981 Gateway Drive  
Pompano Beach, Florida 33069

**Contact:** Kathleen Lavender  
Director of Quality and Compliance

**Telephone Number:** 954.917.9570 x 283  
**Email:** klavender@imiweb.com

**Preparation Date:** November 16, 2017

**Trade Name:** Guarded Luer Connector  
**Device Common Name:** Luer Connector(s)  
**Classification Regulation:** 21 CFR 880.5440  
**Classification Name:** Intravascular Administration Set  
**Class:** II  
**Panel:** General Hospital  
**Product Code:** LHI

**Predicate Device:** TUBING SETS FOR BAXA EXACTA-MED PHARMACY PUMP (K900585)

**Device Description**

The Guarded Luer Connector (GLC) is a polypropylene, sterile device, single use product intended to provide the fluid path for transferring large source container ingredients into smaller containers. The product is offered in two configurations; Female-Female Luer lock (57-400) and Female-Male Luer Lock (57-401); both configurations meet the intended use. The Guarded Luer Connector is a connector for connecting two devices with fittings conforming to ISO 80369-7 for intravascular connectors and ISO 8536-10 for fluid line accessories.

**Indication for Use**

<table>
<thead>
<tr>
<th>SUBJECT (K173577)</th>
<th>PREDICATE (K900585)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td><strong>Indications for Use</strong></td>
</tr>
<tr>
<td>The Guarded Luer Connector is a fluid transfer device used in the pharmacy to provide the fluid path for transferring large source container ingredients into a smaller container</td>
<td>Identical to the FDA cleared 510(k) Indications for Use</td>
</tr>
</tbody>
</table>

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Basis for Substantial Equivalence
The Guarded Luer Connector is substantially equivalent to the connectors in the predicate device, TUBING SETS FOR BAXA EXACTA-MED PHARMACY PUMP (K900585). The devices have the same indications for use, are made of the same material, and are provided sterile. They are both indicated as fluid transfer devices used in the pharmacy to provide the fluid path for transferring large source container ingredients into a smaller container.

The substantial equivalence of the Guarded Luer Connector is adequately supported by the testing rationale and data provided, materials information, and comparison of design characteristics as found in the comparison table below. The testing provided supports the equivalence of the Guarded Luer Connector to the predicate, and shows no new questions of safety and effectiveness have been introduced with this device.

Comparison Between the Guarded Luer Connector and the Predicate Device:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Proposed Device K173577</th>
<th>Predicate Device K900585</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proprietary Device Name</td>
<td>Guarded Luer Connector</td>
<td>TUBING SETS FOR BAXA EXACTA-MED PHARMACY PUMP</td>
</tr>
<tr>
<td>Company Name</td>
<td>International Medical Industries, Inc.</td>
<td>BAXA CORP.</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Guarded Luer Connector is a fluid transfer device used in the pharmacy to provide the fluid path for transferring large source container ingredients into a small container(s).</td>
<td>The Rapid-Fill Tubeset, manufactured by Baxa (Baxter) Corporation, is a fluid transfer device used in the pharmacy to provide the fluid path for transferring large source container ingredients into a small container(s).</td>
</tr>
<tr>
<td>Product Code</td>
<td>LHI</td>
<td>LHI</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>21 CFR 880.5440</td>
<td>21 CFR 880.5440</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Ethylene Oxide, SAL 10^-6</td>
<td>Ethylene Oxide</td>
</tr>
<tr>
<td>Number of Uses</td>
<td>Single Use, RX Only</td>
<td>Single Use, RX Only</td>
</tr>
<tr>
<td>Closure Cap Material</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Per ISO 10993-1 for prolonged duration, external communicating indirect blood path</td>
<td>From 510(k) summary: Per ISO 10993-1 for prolonged duration, external communicating, indirect blood path</td>
</tr>
<tr>
<td>Connection</td>
<td>Female Luer Lock to Female Luer Lock</td>
<td>Female Luer Lock to Female Luer Lock</td>
</tr>
</tbody>
</table>
Technological Characteristics

The Guarded Luer Connector is an injection molded Luer connector component made of Polypropylene and colorant. The intended use and function of the proposed Guarded Luer Connector is identical to the predicate device in design and operation. The primary difference between the proposed device and the predicate device is that proposed product contains two configurations; Female-to-Female Luer connector (GLC 57-400) or Female-to-Male Luer connector (GLC 57-401). The second difference in the proposed device is that the outer guards of device have a recessed section to visually distinguish the device from the predicate while still allowing for a contact-free surface, reducing the potential for contamination during use equivalent to the predicate. The proposed device's intended use and function are the same as that of the predicate device. The two differences are in the proposed device's design. The first difference, the additional configuration, does not negatively impact the safety or efficacy of the device as the connections are the same as the predicate device in that they are luer lock. The second difference, the recessed design feature, is for a visual distinction from the predicate device and does not affect the device's functionality nor does it negatively impact safety or effectiveness. Furthermore, the proposed device was tested to the same testing requirements as the predicate device.

Performance Data

Guarded Luer Connector meets the bench testing requirements per ISO 80369-7 Small-bore connectors for Liquids and Gases in Healthcare Applications – Part 7: Connectors with 6% (Luer) Taper for Intravascular of Hypodermic Applications and ISO 8536-10 Infusion Equipment for Medical Use – Accessories for fluid lines for single use with pressure infusion equipment. Compliance with these international standards demonstrates that the proposed cap device is substantially equivalent to the predicate device. Sterilization by Ethylene Oxide has been validated for Guarded Luer Connectors. A summary of the performance tests performed is presented below. All pre-determined acceptance criteria were met.

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 80369-7:2016</td>
<td>Design verification to ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications</td>
</tr>
<tr>
<td>Shipping Shelf Life Evaluation</td>
<td>Design verification of the shelf life</td>
</tr>
<tr>
<td>Resistance to Override</td>
<td>Engineering study of torque performance specification for evaluation of predicate device</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| ANSI/AAMI/ISO 11737-2:2009 (R) 2014 | *Sterilization of medical devices – Microbiological methods – part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process*  
  - Removal of microorganisms from product and transfer of removed microorganisms to growth medium followed by incubation |
| 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*  
  - Met 10⁻⁶ SAL requirement |
| ANSI/AAMI ST72:2011 | *Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing*  
  - *Limulus* Amoebocyte Lysate test - <2.0 EU/device |
Biocompatibility Testing

The device Guarded Luer Connector passed all biocompatibility tests. In accordance to Guidance Document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"; Guidance for Industry and Food and Drug Administration Staff, Jun 16, 2016, the following biocompatibility tests were required and therefore performed for a Surface device, Skin/Blood Path, Indirect Contact, Prolonged Duration: Cytotoxicity, Sensitization, Irritation / Intracutaneous Reactivity, Acute Systemic Toxicity, Materials Mediated Pyrogenicity and Hemocompatibility.

Conclusion
Review of the in-vitro performance test data as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility demonstrate that the subject device, Guarded Luer Connector (GLC) is substantially equivalent to the connectors cited in the predicate device TUBING SETS FOR BAXA EXACTA-MED PHARMACY PUMP. Any differences between the subject and the predicate devices do not raise any issues of safety and effectiveness.