December 29, 2016

Berpu Medical Technology Co., Ltd
% Diana Hong
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai 200120
CHINA

Re: K162180
  Trade/Device Name: Disposable Insulin Syringe
  Regulation Number: 21 CFR 880.5860
  Regulation Name: Piston Syringe
  Regulatory Class: II
  Product Code: FMF
  Dated: November 28, 2016
  Received: December 2, 2016

Dear Diana Hong:

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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm). 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](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](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)*
K162180

Device Name
Disposable Insulin Syringe

Indications for Use *(Describe)*
The disposable insulin syringe is intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of insulin into parts of the body below the surface skin.

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
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.”
Exhibit #2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number:  K162180

1. Date of Preparation: 12/22/2016

2. Sponsor Identification

   Berpu Medical Technology Co., Ltd
   No. 14 Xingji Road, Yongxing Street, Longwan District, 325000, Wenzhou, Zhejiang Province

   Establishment Registration Number: 3004496829

   Contact Person: Jundong Tan
   Position: Management Representative
   Tel: +86-577-86651999
   Fax: +86-577-86630389
   Email: BERPU@BERPU.COM

3. Designated Submission Correspondent

   Ms. Diana Hong (Primary Contact Person)
   Ms. Ying Xu (Alternative Contact Person)

   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119, Shanghai, 200120, China

   Tel: +86-21-22815850,
   Fax: 240-238-7587
   Email: info@mid-link.net
4. Identification of Proposed Device

Trade Name: Disposable Insulin Syringe
Common Name: Insulin syringe with needle

Regulatory Information

Classification Name: Syringe, Piston;
Classification: II;
Product Code: FMF
Regulation Number: 21CFR 880.5860
Review Panel: General Hospital;

Indication for Use:

The disposable insulin syringe is intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of insulin into parts of the body below the surface skin.

Device Description

The proposed device is a syringe with fixed needle tube which is intended for injection the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin. The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe. The proposed devices are provided sterile, single use.

The proposed device is available in 0.3ml, 0.5ml and 1ml volumes.

5. Identification of Predicate Device

510(k) Number: K072739
Product Name: Sterile Insulin Syringe for single use with fixed needle
Manufacturer: ShanDong Weigao Group Medical Polymer Products Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test provided in this submission include:
Physical, Mechanical and Chemical Tests performed on the proposed device


Cleanliness Clause 4 of ISO 7864:1993
Limits for acidity or alkalinity Clause 5 of ISO 7864:1993
Limits for extractable metals Clause 6 of ISO 7864:1993
Size designation Clause 7 of ISO 7864:1993
Colour coding Clause 8 of ISO 7864:1993
Needle hub Clause 9 of ISO 7864:1993
Sheath Clause 10 of ISO 7864:1993
Needle tube Clause 11 of ISO 7864:1993
Needle point Clause 12 of ISO 7864:1993
Performance Clause 13 of ISO 7864:1993

Freedom from extraneous matter Clause 5 of ISO 8537:2007
Limits for extraneous matter Clause 6 of ISO 8537:2007
Lubrication of syringes and needles Clause 7 of ISO 8537:2007
Range of size Clause 8 of ISO 8537:2007
Graduated scale Clause 9 of ISO 8537:2007
Barrel Clause 10 of ISO 8537:2007
Piston/plunger assembly Clause 11 of ISO 8537:2007
Needle tubing and needles Clause 13 of ISO 8537:2007
Dose Accuracy testing Clause 9.1 of ISO 8537:2007

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength ASTM F88/F88-09
Internal pressure ASTM F1140/F1140M-13
Dye penetration ASTM F 1929-12
Sterilization and Shelf Life Testing performed on the proposed device:

SAL 10^6
Validation method ISO 11135:2014
EO residue ISO 10993-7:2008
ECH residue ISO 10993-7:2008
Bacteria Endotoxin Limit USP 38-NF 33 <85>
LAL Pyrogen Test ISO 10993-11:2006
Shelf Life Evaluation Physical, Mechanical, Chemical, Package and Sterility
Tests were performed on accelerated aging samples to verify the claimed shelf life of the device

Biocompatibility Testing

The patient-contact materials of Disposable Insulin Syringe are identified and biocompatibility testing is performed according to ISO 10993 standards

7. Clinical Test Conclusion

No clinical study is included in this submission.
8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

| Item                      | Proposed Device | Predicate Device
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code</td>
<td>FMF</td>
<td>Same K072739</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>21CFR 880.5860</td>
<td>Same</td>
</tr>
<tr>
<td>Classification</td>
<td>II</td>
<td>Same</td>
</tr>
<tr>
<td>Indication for Use</td>
<td>The disposable insulin syringe is intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of insulin into parts of the body below the surface skin.</td>
<td>The sterile insulin syringe for single use with fixed needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin</td>
</tr>
<tr>
<td>Configuration and Material</td>
<td>Configuration</td>
<td>Material</td>
</tr>
<tr>
<td>Protective end cap</td>
<td>Polypropylene (PP)</td>
<td>Polypropylene (PP)</td>
</tr>
<tr>
<td>Plunger</td>
<td>Polypropylene (PP)</td>
<td>Polypropylene (PP)</td>
</tr>
<tr>
<td>Barrel</td>
<td>Polypropylene (PP)</td>
<td>Barrel</td>
</tr>
<tr>
<td>Piston</td>
<td>Polyisoprene Rubber</td>
<td>Piston</td>
</tr>
<tr>
<td>Needle</td>
<td>Stainless Steel (SUS304)</td>
<td>Needle</td>
</tr>
<tr>
<td>Needle cover</td>
<td>Polypropylene (PP)</td>
<td>Needle cover</td>
</tr>
<tr>
<td>Syringe Volume</td>
<td>0.3ml, 0.5ml, 1.0ml</td>
<td>0.5ml, 1.0ml</td>
</tr>
<tr>
<td>Needle Diameter</td>
<td>0.25mm, 0.30mm, 0.33mm, 0.36mm, 0.40mm</td>
<td>0.30mm, 0.33mm, 0.36mm</td>
</tr>
<tr>
<td>Needle Length</td>
<td>5mm, 6mm, 8mm, 12mm</td>
<td>Unknown</td>
</tr>
<tr>
<td>Performance Test</td>
<td>Comply with ISO 9626, ISO 7864, ISO 8536</td>
<td>Same</td>
</tr>
<tr>
<td>Sterile</td>
<td>EO Sterilized</td>
<td>Same</td>
</tr>
<tr>
<td>Single Use</td>
<td>Single Use</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Cytotoxicity</td>
<td>No cytotoxicity</td>
</tr>
<tr>
<td></td>
<td>Irritation</td>
<td>No irritation reactivity</td>
</tr>
<tr>
<td></td>
<td>Sensitization</td>
<td>No significant evidence of skin sensitization</td>
</tr>
<tr>
<td></td>
<td>Systemic Toxicity</td>
<td>No significant evidence of systemic toxicity</td>
</tr>
<tr>
<td></td>
<td>Hemolysis</td>
<td>No evidence of hemolysis</td>
</tr>
</tbody>
</table>

Conform with ISO 10993
9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.