September 12, 2017

Medbio LLC.
\% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc
690 Roosevelt
Irvine, California 92620

Re: K171144
   Trade/Device Name: Medifine Pen Needle 3 Bevel, Medifine Pen Needle Quinta 5 Bevel
   Regulation Number: 21 CFR 880.5570
   Regulation Name: Hypodermic Single Lumen Needle
   Regulatory Class: Class II
   Product Code: FMI
   Dated: August 1, 2017
   Received: August 8, 2017

Dear Priscilla Chung:

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

Lori Wiggins, MPT, CLT
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)
K171144

Device Name
Medifine Pen Needle 3 Bevel, Medifine Pen Needle Quinta 5 Bevel

Indications for Use (Describe)
The Medifine Pen Needle 3 Bevel and the Medifine Pen Needle Quinta 5 Bevel are indicated for use with a pen injector device for the subcutaneous injection of insulin.

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
PRAS Staff@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.”
510(K) SUMMARY
(K171144)

1. **510k Submitter**

   MEDBIO LLC.
   4846 Citrus Way
   Cooper City, Florida 33330, U.S.A
   
   September 8, 2017

2. **US Agent/Contact Person:**

   Priscilla Chung
   LK Consulting Group USA, Inc.
   690 Roosevelt, Irvine CA 92620
   Email: juhee.c@lkconsultinggroup.com

3. **Device Name:**

   - Trade Name: Medifine Pen Needle 3 Bevel
   - Trade Name: Medifine Pen Needle Quinta 5 Bevel
   - Classification: Class II
   - Regulation Description: Hypodermic single lumen needle
   - Product Code: FMI
   - Regulation Number: 21 CFR 880.5570
   - Review Panel: General Hospital

3. **Predicate Device:**

   CareFine Pen Needle (K140568) manufactured by Facet Technologies, LLC

4. **Device Description:**

   The Medifine Pen Needle consists of a needle with hub, and shield assembly. The needle shield is intended to provide physical protection to the needle with the hub. Blister paper covers the primary container. The primary container maintains sterility of the needle covering the hub and the shield with the blister paper. The needle hub can be connected onto the pen injector device for the subcutaneous injection of insulin. The device offers two compatible types of needle (patient contact point) as below. The user can choose the needle as per their preference.

5. **Indications For Use:**

   The Medifine Pen Needle 3 Bevel and the Medifine Pen Needle Quinta 5 Bevel are indicated for use with a pen injector device for the subcutaneous injection of insulin.
6. **Technological Characteristics:**

The Medifine Pen Needle 3 Bevel and Medifine Pen Needle Quinta 5 Bevel is substantially equivalent to the CareFine Pen Needle (K140568) by Facet Technologies, LLC. The manufacturer of the predicate device and the subject device is the same, TAE-CHANG INDUSTRIAL CO., LTD. The subject device and the predicate device are identical including manufacturing facility and manufacturing processes.

<table>
<thead>
<tr>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
</table>
| **Device Name** | Medifine Pen Needle 3 Bevel  
Medifine Pen Needle Quinta 5 Bevel | CareFine Pen Needle |
| **Manufacturer** | TAE-CHANG INDUSTRIAL CO., LTD | TAE-CHANG INDUSTRIAL CO., LTD |
| **510k Applicant** | MEDBIO LLC. | Facet Technologies, LLC |
| **Product Code** | FMI | FMI |
| **510k Number** | K171144 | K140568 |
| **Indications for use** | The Medifine Pen Needle 3 Bevel and the Medifine Pen Needle Quinta 5 Bevel are indicated for use with a pen injector device for the subcutaneous injection of insulin. | The CareFine Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin. |
| **Structure** | Cannula / Hub / Needle Cap / Primary Container | Cannula / Hub / Needle Cap / Primary Container |
| **Principle of Operation** | Pen needle is indicated for use with pen injector devices for the subcutaneous injection of insulin. | Pen needle is intended for use with pen injector devices for the subcutaneous injection of insulin. |
| **Shape** | ![Image] | ![Image] |
| **Needle Tube Length** | 4mm, 5mm, 6mm, 8mm, 12.7mm | 4mm, 5mm, 6mm, 8mm, 12.7mm |
| **Needle Tube Material** | Stainless steel | Stainless steel |
| **Needle Hub Material** | Polypropylene | Polypropylene |
| **Needle shield Material** | Polyethylene | Polyethylene |
| **Primary container Material** | Polypropylene | Polypropylene |
| **Tip Configuration (Patient Side)** | 3 Bevel | 3 Bevel |
The following tests were performed on the Medifine Pen Needle 3 Bevel and Medifine Pen Needle Quinta 5 Bevel and the test results show that the subject device is substantially equivalent to the predicate devices in the market.

<table>
<thead>
<tr>
<th>No</th>
<th>Test item</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dimensions</td>
<td>ISO 11608-2:2012 Clause 4.2.1 General</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ISO 9626 1991_Amd2001, clause8</td>
</tr>
<tr>
<td>2</td>
<td>Dimensions for needles</td>
<td>ISO 11608-2:2012 Clause 4.2.2 Dimensions for needles</td>
</tr>
<tr>
<td>3</td>
<td>Determination of flow rate through the needle</td>
<td>ISO 11608-2:2012 Clause 4.3 Determination of flow rate through the needle</td>
</tr>
<tr>
<td>4</td>
<td>Bond between hub and needle tube</td>
<td>ISO 11608-2:2012 Clause 4.4 Bond between hub and needle tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ISO 7864 Clause 13.1</td>
</tr>
<tr>
<td>5</td>
<td>Needle points</td>
<td>ISO 11608-2:2012 Clause 4.5 Needle point</td>
</tr>
<tr>
<td>6</td>
<td>Freedom from defects</td>
<td>ISO 11608-2:2012 Clause 4.6 Freedom from defects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ISO 7864 Clause 11.3</td>
</tr>
<tr>
<td>7</td>
<td>Lubrication</td>
<td>ISO 11608-2:2012 Clause 4.7 Lubrication</td>
</tr>
<tr>
<td>8</td>
<td>Dislocation of measuring point at patient end</td>
<td>ISO 11608-2:2012 Clause 4.8 Dislocation of measuring point at patient end</td>
</tr>
<tr>
<td>11</td>
<td>Compatibility of</td>
<td>ISO 11608-2:2012 Clause 11</td>
</tr>
</tbody>
</table>

7. Testing
8. **Conclusion**

Based on the information provided in this premarket notification, MEDBIO LLC. concludes that the Medifine Pen Needle 3 Bevel and Medifine Pen Needle Quinta 5 Bevel are substantially equivalent to predicate device.