Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number:  **K150758**

1. Date of Preparation: 05/22/2015

2. Sponsor Identification

   **Jiangyin Caina Technology Co., Ltd.**  
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   Establishment Registration Number: 3005670221

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   Position: General Manager  
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   Email: jun.lu@cainamedical.com

3. Identification of Proposed Device

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

   **Regulatory Information**

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

   **Intended Use Statement:**

   Safelock Disposable Insulin Syringe is intended to inject U-100 insulin into the human body and aid in the prevention of accidental needle stick injuries.

   **Device Description**

   Safelock Disposable Insulin Syringes are provided sterile, single use, which consist of five pieces
components: (1) a syringe barrel calibrated in units of insulin (U-100) with a permanently attached single lumen needle on it, (2) a needle cap, (3) plunger and (4) protective end cap and (5) an additional safety mechanism installed at the needle end of the syringe.

The devices are available in different combination of syringe volumes and needle sizes.

4. Identification of Predicate Device

510(k) Number: K103011  
Product Name: UltiMed UltiCare Safety Insulin Syringe  
Manufacturer: UltiMed Inc

5. Identification of Reference Device

510(k) Number: K113091  
Product Name: Syringes and Needles  
Manufacturer: Jiangyin Caina Technology Co., Ltd.

The patient contact materials of the proposed device are identical to those of the legally marketed device, Syringes and Needles, as cleared in K113091 on 10/28/2011, which is also manufactured by Jiangyin Caina Technology 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 tests provided in this submission include:

**Physical, Mechanical and Chemical Tests performed on the proposed device (Syringe):**

- Freedom from extraneous matter  
  Clause 5 of ISO 8537:2007
- Limits for acidity and alkalinity  
  Clause 6.1 of ISO 8537:2007
- Limits for extractable metals  
  Clause 6.2 of ISO 8537:2007
- Lubrication of syringes and needles  
  Clause 7 of ISO 8537:2007
- Range of sizes  
  Clause 8 of ISO 8537:2007
- Scale  
  Clause 9.1 of ISO 8537:2007
- Numbering of scale  
  Clause 9.2 of ISO 8537:2007
- Dimensions  
  Clause 10.1 of ISO 8537:2007
- Finger grips  
  Clause 10.2 of ISO 8537:2007
- Piston/plunger assembly  
  Clause 11.1 of ISO 8537:2007
- Fit of piston in barrel  
  Clause 11.2 of ISO 8537:2007
- Needle tubing for syringes  
  Clause 13.2 of ISO 8537:2007
- Dead space  
Freedom from leakage at needle Clause 14.2 of ISO 8537:2007
Liquid and air leakage past piston Clause 14.3 of ISO 8537:2007

Physical, Mechanical and Chemical Tests performed on the proposed device (Needle):


Sterile Barrier Packaging Testing performed on the proposed device:

- Seal strength ASTM F88/F88M-09
- Internal pressure ASTM F1140/F1140M-13

Sterilization and Shelf Life Testing performed on the proposed device:

- EO residue ISO 10993-7:2008
- ECH residue ISO 10993-7:2008
- Bacteria Endotoxin Limit USP37-NF 32,<85>
- Shelf Life Evaluation Physical, Mechanical Chemical, Package and Sterility Tests were performed on accelerated aged samples to verify the claimed shelf life of the device.

Biocompatibility Testing:

The patient-contact materials of Safelock Disposable Insulin Syringes devices are identical to the previously cleared Syringes and Needles (K113091), and therefore additional biocompatibility testing to ISO 10993 standards is not required.

Simulate Clinical Study performed on the proposed device:

A simulated clinical study was performed according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005, to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Safety Feature Testing performed on the proposed device:
Safety feature tests were performed on the proposed device to determine the force to activate the safety mechanism (Protective shield) and the force to detach/destroy the safety mechanism (Protective shield). The results demonstrated that the performances of the safety mechanism of proposed device met the pre-established criteria.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed device</th>
<th>Predicate Device</th>
<th>Reference Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>Safelock Disposable Insulin Syringe</td>
<td>UltiMed UltiCare Safety Insulin Syringe</td>
<td>Syringes and Needles</td>
</tr>
<tr>
<td>Product Code</td>
<td>MEG, FMF</td>
<td>MEG, FMF, FMI</td>
<td>/</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21 CFR 880.5860</td>
<td>21 CFR 880.5860 &amp; 880.5570</td>
<td>/</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Safelock disposable insulin syringe is intended to inject U-100 insulin into the human body and aid in the prevention of accidental needle stick injuries.</td>
<td>The UltiCare Safety Insulin Syringe is intended to inject U-100 insulin into the body. The safety mechanism aids in the prevention of needle stick injuries.</td>
<td>/</td>
</tr>
<tr>
<td>Feature</td>
<td>Orange Needle cap, Fixed Needle; Piston; Plunger; Barrel; Orange Protective end cap; Safety feature</td>
<td>Orange Needle cap, Fixed Needle; Piston; Plunger; Barrel; Orange Protective end cap; Safety feature (Protective shield)</td>
<td>/</td>
</tr>
<tr>
<td>Sterile</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>Color Coding</td>
<td>Yes</td>
<td>Yes</td>
<td>/</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Conforms to the requirement of ISO 10993 series Standards</td>
<td>Conforms to the requirement of ISO 10993 series Standards</td>
<td>Conforms to the requirement of ISO 10993 series Standards</td>
</tr>
<tr>
<td>Patient contact</td>
<td>Plunger PP (polypropylene)</td>
<td>Unknown</td>
<td>PP (polypropylene)</td>
</tr>
<tr>
<td></td>
<td>Barrel PP (polypropylene)</td>
<td>Unknown</td>
<td>PP (polypropylene)</td>
</tr>
</tbody>
</table>
Based on the comparison, the intended use, features and safety mechanism of proposed devices are determined to be Substantially Equivalent (SE) to the predicate device, K103011; both the proposed device and predicate device, K103011, are complied with FDA recognized performance standard, ISO 8537:2007 and ISO 9626:1991, AMENDMENT 1 2001. Comparison tests were also performed to demonstrate that the performance of safety mechanism of both proposed device and predicate device, K103011, are substantially equivalent. The materials used in predicate device, K103011, were not available, materials of proposed devices are not compared with those of predicate device, K103011; however, materials used in the proposed devices are exactly identical to the reference device, K113091.

<table>
<thead>
<tr>
<th>material</th>
<th>Piston</th>
<th>Polysoprene</th>
<th>Unknown</th>
<th>Polysoprene</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle</td>
<td>304 Stainless steel</td>
<td>Stainless steel</td>
<td>304 Stainless steel</td>
<td></td>
</tr>
<tr>
<td>Lubricant</td>
<td>Polydimethylsiloxane</td>
<td>Unknown</td>
<td>Polydimethylsiloxane</td>
<td></td>
</tr>
</tbody>
</table>