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.
No.2, Taifu Road, Huashi Town, Jiangyin, Jiangsu, 214421, China

Establishment Registration Number: 3005670221

Contact Person: Jun Lu
Position: General Manager
Tel: +86-510-86205183
Fax: +86-510-86215183
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	Clause 14.1 of ISO 8537:2007

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):

Materials	Clause 3 of ISO 9626:1991/AMD-1:2001
Surface finish	Clause 4 of ISO 9626:1991/AMD-1:2001
Cleanliness	Clause 5 of ISO 9626:1991/AMD-1:2001
Limits for acidity and alkalinity	Clause 6 of ISO 9626:1991/AMD-1:2001
Size designation	Clause 7 of ISO 9626:1991/AMD-1:2001
Dimensions	Clause 8 of ISO 9626:1991/AMD-1:2001
Stiffness	Clause 9 of ISO 9626:1991/AMD-1:2001
Resistance to breakage	Clause 10 of ISO 9626:1991/AMD-1:2001
Resistance to corrosion	Clause 11 of ISO 9626:1991/AMD-1:2001

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 10933-7:2008
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 1 Comparison between proposed device and predicate device

Item		**Proposed device**	**Predicate Device** K103011	**Reference Device** K113091
Product		Safelock Disposable Insulin Syringe	UltiMed UltiCare Safety Insulin Syringe	Syringes and Needles
Product Code		MEG, FMF	MEG, FMF, FMI	/
Regulation Number		21 CFR 880.5860	21 CFR 880.5860 &21 CFR 880.5570	/
Intended Use		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.	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.	/
Feature		Orange Needle cap, Fixed Needle; Piston; Plunger; Barrel; Orange Protective end cap; Safety feature	Orange Needle cap, Fixed Needle; Piston; Plunger; Barrel; Orange Protective end cap; Safety feature (Protective shield)	/
Sterile		Yes	Yes	/
Single Use		Yes	Yes	/
Color Coding		Yes	Yes	/
Performance		ISO 9626:1991, AMENDMENT 1 2001 ISO 8537:2007	ISO 9626:1991, AMENDMENT 1 2001 ISO 8537:2007	/
Biocompatibility		Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
Patient contact	Plunger	PP (polypropylene)	Unknown	PP (polypropylene)
	Barrel	PP (polypropylene)	Unknown	PP (polypropylene)

material	Piston	Polysoprene	Unknown	Polysoprene
	Needle	304 Stainless steel	Stainless steel	304 Stainless steel
	Lubricant	Polydimethylsiloxane	Unknown	Polydimethylsiloxane

9. Substantially Equivalent (SE) Conclusion

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.