August 17, 2022

Shandong Zhushi Pharmaceutical Group Co., Ltd
% Bruce Cai
Technical Manager
Humiss lnc.
5#501, No. 445, Renmin Road, Qingcun Town, Fengxian District
Shanghai, 201414
China

Re: K212033
Trade/Device Name: Disposable Sterile Syringe, with/without needle; luer/luer-lock: Sterile Insulin Syringe for Single use, with needle: Sterile Hypodermic needle for Single use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: July 5, 2022
Received: July 11, 2022

Dear Bruce Cai:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Alan M. Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212033

Device Name
Disposable Sterile Syringe, with/without needle; luer/luer-lock

Indications for Use *(Describe)*
The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212033

Device Name

Sterile Insulin Syringe for Single use, with needle

Indications for Use *(Describe)*

The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-100, 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.

The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-40 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.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212033

Device Name
Sterile Hypodermic needle for Single use

Indications for Use *(Describe)*
The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

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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K212033 510(k) SUMMARY

I. PREPARATION DATE: August 8, 2022

II. SUBMITTER

Manufacturer name: Shandong Zhushi Pharmaceutical Group Co., Ltd.
Address; No. 6, Shande Road, Shan County, Heze City, Shandong Province, 274300, China
Contact Person: Junhui Zhu
Title: Manager
Tel: +86-15764021131
Fax: +86-530-4265777
E-mail: 2307426957@qq.com

III. Correspondent Contact Information

Bruce Cai (Contact Person)
Humiss Inc.
Tel: +86-13585598660
E-mail: cc401vip@126.com
Summary Preparation Date: 2021.4.21

IV. DEVICE

Name of Device:	- Disposable Sterile Syringe, with/without needle; luer/luer-lock - Sterile Insulin Syringe for Single use, with needle - Sterile Hypodermic needle for Single use
Common Name	- Disposable Sterile Syringe - Disposable insulin syringe - Disposable Hypodermic needle
Classification Name	- Piston Syringe - Piston Syringe - Hypodermic Single Lumen Needle
Regulation Number	- 21 CFR 880.5860 - 21 CFR 880.5860 - 21 CFR 880.5570
Product Code	- FMF - FMF - FMI
Device Class	- Class II

V. PREDICATE DEVICE

K190002- Sterile Hypodermic Syringe for Single use with/without needle,

Sterile Insulin Syringe for Single use with needle,
Sterile Hypodermic needle for Single use.

VI. Device Description

Table 5.1. Device Description Summary for Disposable Sterile Syringe

Models	Subject Device
Product name	Disposable Sterile Syringe, with/without needle; luer/luer-lock
Indications for use	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.
Configuration	Piston, Plunger, Barrel
Sterility condition	EO Sterilized
Environment of use	Prescription use
Intended users	Medical professionals and trained care givers
Single use	Yes
Operation mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.
Length	83-152mm
Diameter	50-31mm
Tip type	luer/luer-lock
Needle tip configuration	The blade angle of the injection needle is the long bevel angle.
Nozzle type	Luer / Lock, %6 conical, 1,2 mm
Barrel marking specs	0.01ml-0.5ml
Graduation legibility	Legible
Needle cover dimensions	
Needle cover color	Transparent
Lubricant composition	Dimethicone
Barrel transparency	Transparent/ UV resistant
Needle cover strength	15N (min. 2N max. 15N)
Hub/needle bond strength	min. 22-69 N
Product performance	Complied with ISO 7886-1, ISO 7864, ISO 9626
Volume	1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 25mL, 30mL, 50mL
Sizes	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G
Needle Lengths	13-38 mm
Piston material	Isoprene Rubber
Barrel material	PP
Plunger material	PP

Needle material	PP, SUS304
SAL	10^{-6}
Endotoxin Limit	20 EU per device
Biocompatibility	Complied with ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Hemolytical effect)

Table 5.2. Device Description Summary for Insulin Syringe

Models	**Subject Device**
Product name	Sterile Insulin Syringe for Single use, with needle
Indications for use	The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-100, 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. The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-40 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.
Configuration	Needle Cap, Needle, Piston, Plunger, Barrel, End Cap
Sterility condition	EO Sterilized
Environment of use	Prescription use
Single use	Yes
Operation mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.
Product performance	Complied with ISO 8537
Volume	0.5ml, 1ml volumes with fixed needle
Needle Lengths	8mm
Piston material	Isoprene Rubber
Barrel material	PP
Plunger material	PP
Needle material	SUS304
Needle Cap material	PE
End Cap material	PE
SAL	10^{-6}
Endotoxin Limit	20 EU per device
Biocompatibility	ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Subchronic Toxicity, Hemolytical effect

Table 5.3. Device Description Summary for Needle

Models	**Subject device**

Product name	Sterile Hypodermic needle for Single use
Indications for use	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.
Configuration	Protective cap, Needle, Adhesives, Needle hub
Sterility condition	EO Sterilized
Environment of use	Prescription use
Intended users	Medical professionals and trained care givers
Configuration	Protective cap, Needle, Adhesives, Needle hub
Single use	Yes
Operation mode	For Manual Use Only, For Single Use only
Product performance	Complied with: ISO 7864, ISO 9626
Sizes	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 30G
Needle Lengths	13-38 mm
Protective cap materials	PP
Adhesive	Epoxy resin
Needle Hub materials	PP
Needle material	SUS304
SAL	10^{-6}
Endotoxin Limit	20 EU per device
Biocompatibility	Complied with ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Hemolytical effect)

VII. Predicate Comparison

Table 6.1 Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock Predicate Comparison

Models	**Subject Device**	**Predicate Device K190002**	**Comparison**
Product name	Disposable Sterile Syringe, with/without needle; luer/luer-lock	Sterile Hypodermic Syringe for Single use, with/without needle	Similar
Product code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Indications for use	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw	Same

	from body.	fluid from body.	
Configuration	Piston, Plunger, Barrel	Piston, Plunger, Barrel	Same
Sterility condition	EO Sterilized	EO Sterilized	Same
Environment of use	Prescription use	Prescription use	Same
Intended users	Medical professionals and trained care givers	Medical professionals and trained care givers	Same
Single use	Yes	Yes	Same
Operation mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	Same
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Product performance	Complied with ISO 7886-1, ISO 7864, ISO 9626	Complied with ISO 7886-1, ISO 7864, ISO 9626	Same
Volume	1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 25mL, 30mL, 50mL	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml and 60 ml	Difference 1
Sizes	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Difference 2
Needle Lengths	13-38 mm	4-38 mm	Difference 3
Patient contact component and material			
Piston	Isoprene Rubber	Isoprene Rubber	Same
Barrel	PP	PP	Same
Plunger	PP	PP	Same
Needle	PP, SUS304	PP, SUS304	Same
Sterilization			
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Table 6.2. Sterile Insulin Syringe for Single use, with needle Predicate Comparison

Models	**Subject Device**	**Predicate Device K190002**	
Product name	Sterile Insulin Syringe for Single use, with needle	Disposable insulin syringe	Same

Product code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Indications for use	The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-100, 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. The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-40 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.	The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-100, 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. The sterile insulin syringe for single use with needle, with the calibration unit of insulin for U-40 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.	Same
Configuration	Needle Cap, Needle, Piston, Plunger, Barrel, End Cap	Needle Cap, Needle, Piston, Plunger, Barrel, End Cap	Same
Sterility condition	EO Sterilized	EO Sterilized	Same
Environment of use	Prescription use	Prescription use	Same
Intended users	Patient use	Patient use	Same
Single use	Yes	Yes	Same
Operation mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the	Same

		patient.	
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Product performance	Complied with ISO 8537	Complied with ISO 8537	Same
Volume	0.5ml, 1ml volumes with fixed needle	0.3ml, 0.5ml, 1ml volumes with fixed needle	Difference 4
Needle Lengths	8mm	8mm, 13mm	Difference 5
Patient contact component and material			
Piston	Isoprene Rubber	Isoprene Rubber	Same
Barrel	PP	PP	Same
Plunger	PP	PP	Same
Needle	PP, SUS304	PP, SUS304	Same
Needle cap / End Cap	PE/PE	PP/PP	Difference 6
Sterilization			
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Table 6.3. Sterile Hypodermic needle for Single use Predicate Comparison

Models	**Subject Device**	**Predicate Device K190002**	
Product name	Sterile Hypodermic needle for Single use	Sterile Hypodermic needle for Single use	
Product code	FMI	FMI	
Regulation number	21 CFR 880.5570	21 CFR 880.5570	
Class	II	II	
Intended users	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	
Configuration	Protective cap, Needle, Adhesives, Needle hub	Protective cap, Needle, Adhesives, Needle hub	
Sterility condition	EO Sterilized	EO Sterilized	
Environment of use	Prescription use	Prescription use	
Single use	Yes	Yes	

Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	
Product performance	Complied with: ISO 7864, ISO 9626	Complied with: ISO 7864, ISO 9626	
Sizes	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Difference 7
Needle Lengths	13-38 mm	4-38 mm	Difference 8
Protective cap materials	PP	PP	
Adhesive	Epoxy resin	Epoxy resin	
Needle Hub	PP	PP	
Needle material	SUS304	SUS304	
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

VIII. Substantial Equivalence Discussion

7.1 Disposable Sterile Syringe Discussion

The indications for use statement for the Disposable Sterile Syringe subject device are identical to the predicate device. There are no technological differences between the predicate and subject devices except for the following: syringe volumes, needle gauge sizes, needle lengths.

- Difference 1: The subject device includes different syringe volumes compared to the predicate. The subject device includes 2mL, 2.5mL, 25mL volume syringes while the predicate does not include these sizes. The predicate device includes 6ml, 35ml and 60 ml syringe volumes which the subject device does not include. These slight differences have no adverse effect on clinical safety and performance. All the subject device hypodermic syringes are tested in accordance with ISO 7886-1 standard. The requirements of the standards are met.
- Difference 2: The subject device does not include needle gauges 28G, 29G, 30G while the predicate device includes these sizes. The needles are tested in accordance with ISO 7864 and ISO 9626 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864 and ISO 9626.
- Difference 3: The predicate device includes additional needle lengths compared to the subject device. The subject device includes the following additional needle lengths: 13-38 mm. The needles are tested in accordance to ISO 7864 and ISO 9626 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864 and ISO 9626.

7.2 Insulin Syringe Discussion

The indications for use statement for the Sterile Insulin Syringe are identical to the predicate

device. There are no technological differences between the subject and the predicate device except for the following: syringe volumes, needle lengths and Needle cap/End Cap material. This was verified by performance testing according to ISO 8537. The intended use, principle of operation, materials, specifications, and sterilization information for the subject device are the same as for the predicate device. Therefore, it can be determined that the proposed device is substantially equivalent to the predicate device.

- Difference 4: The subject device includes different syringe volumes compared to the predicate. The subject device does not include 0.3ml volume syringes while the predicate includes this size. These slight differences have no adverse effect on clinical safety and performance. The subject device insulin syringe is tested in accordance with ISO 8537 standard. The requirements of the standards are met.
- Difference 5: The subject device includes different syringe volumes compared to the predicate. The subject device does not include 13mm needle while the predicate includes this length. These slight differences have no adverse effect on clinical safety and performance. The subject device insulin syringe is tested in accordance with ISO 8537 standard. The requirements of the standards are met.
- Difference 6: The Needle cap and End Cap of the subject device is PE, while the predicate device material is PP. Biocompatibility studies are carried out in according to ISO 10993-1. Biological safety was demonstrated. The intended use, principle of operation, and sterilization information for the subject device are the same as the predicate device. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Therefore, it can be determined that the proposed device is substantially equivalent to the predicate device.

7.3 Needle Discussion

The indications for use statement for the subject device is identical to the predicate device. There are no technological differences between the subject and the predicate device except for the following: needle gauge sizes and needle length.

- Difference 7: The subject device includes additional needle gauges compared to the predicate. The subject device does not include needle gauges 29G while the predicate device includes these sizes. The needles are tested in accordance with ISO 7864 and ISO 9626 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864 and ISO 9626.
- Difference 8: The predicate device includes additional needle lengths compared to the subject device. The subject device includes the following additional needle lengths: 13-38 mm. The needles are tested in accordance to ISO 7864 and ISO 9626 and released in accordance with the standards compliance. This was verified by performance testing according to ISO 7864 and ISO 9626.

VIV. Performance Testing

8.1 Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock

The Sterile Hypodermic Syringe for Single use described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 7864:2016 Fourth Edition: Sterile hypodermic needles for single use - Requirements and test methods
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- USP 788 Particulate Matter in Injections
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 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
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

The Sterile Hypodermic Syringe for Single use is considered in the category of "External Communicating Devices" and are accepted to be in contact for a period less than 24 hours with "indirect blood path". Thus, cytotoxicity (ISO 10993-5:2009, irritation and sensitization (ISO 10993-10:2010), acute systemic toxicity (ISO 10993-11:2017), hemocompatibility (EN ISO 10993-4:2017) were carried out for the device in question.

8.2 Sterile Insulin Syringe for Single use, with needle

The Sterile Insulin Syringe for Single use described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 8537 Third edition 2016-03-15 Sterile single-use syringes, with or without needle, for insulin
- ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for

Systemic Toxicity
- USP 788 Particulate Matter in Injections
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 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
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

The Sterile Insulin Syringe for Single use is considered in the category of "External Communicating Devices" and are accepted to be in contact for a period between 24 hours - 30 days because of repetitive use of patient with "indirect blood path". Thus, cytotoxicity (ISO 10993-5:2009, irritation and sensitization (ISO 10993-10:2010), acute systemic toxicity (ISO 10993-11:2017), sub-acute systemic toxicity (ISO 10993-11:2017), sub-chronic systemic toxicity (ISO 10993-11:2017), hemocompatibility (EN ISO 10993-4:2017) were carried out for the device in question.

8.3 Sterile Hypodermic needle

The Sterile Hypodermic needle described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7864:2016 Fourth Edition: Sterile hypodermic needles for single use - Requirements and test methods
- ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- USP 788 Particulate Matter in Injections
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 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
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

The Sterile Hypodermic needle is considered in the category of "External Communicating Devices" and are accepted to be in contact for a period less than 24 hours with "indirect blood path". Thus, cytotoxicity (ISO 10993-5:2009, irritation and sensitization (ISO 10993-10:2010), acute systemic toxicity (ISO 10993- 11:2017), hemocompatibility (EN ISO 10993-4:2017) were carried out for the device in question.

X. Clinical study

No prospective clinical trials were conducted in support of this 510(K).

XI. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject devices are substantially equivalent to the predicate devices with respect to the indications for use, target populations, treatment method, and technological characteristics.