



December 14, 2020

Set Medikal Sanayi Ve Ticaret Anonim Sirketi  
% Mehmet Fatih Ormeci  
Consultant  
Medcer Uluslararası Medikal Belgelendirme Anonim Sirketi  
Taspınar Mahallesi 2800. Caddesi A-2 Apt. No:6 B/49  
Ankara, 06830  
Turkey

Re: K201284

Trade/Device Name: Sterile Hypodermic Syringe for Single Use, 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: November 11, 2020

Received: November 16, 2020

Dear Mehmet Fatih Ormeci:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rumi Young  
Acting 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

## Indications for Use

510(k) Number (if known)

Device Name

Sterile Hypodermic Syringe for Single use, 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)

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## Indications for Use

510(k) Number (if known)

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)

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## Indications for Use

510(k) Number (if known)

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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## K201284 510(k) Summary

510(k) Submitter Name	SET MEDİKAL SANAYI VE TICARET ANONİM ŞİRKETİ
510(k) Submitter Address	Osmangazi Mahallesi Maresal Fevzi Çakmak Caddesi No:18 Esenyurt İstanbul/TURKEY
510(k) Submitter Telephone No	+90-212-622-0400
Primary Correspondent Contact Information	Mehmet Fatih Örmeci (Consultant) +90-532-397-3043 <a href="mailto:mformeci@gmail.com">mformeci@gmail.com</a> Fax Number: +90 (212) 689 4 828
Summary Preparation Date	11/24/2020

Trade Or Proprietary Name	<ul style="list-style-type: none"> <li>- Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock</li> <li>- Sterile Insulin Syringe for Single use, with needle</li> <li>- Sterile Hypodermic needle for Single use</li> </ul>
Common Name	<ul style="list-style-type: none"> <li>- Hypodermic Syringe</li> <li>- Insulin Syringe</li> <li>- Hypodermic needle</li> </ul>
Classification Name	<ul style="list-style-type: none"> <li>- Piston Syringe</li> <li>- Piston Syringe</li> <li>- Hypodermic Single Lumen Needle</li> </ul>
Regulation Number	<ul style="list-style-type: none"> <li>- 21 CFR 880.5860</li> <li>- 21 CFR 880.5860</li> <li>- 21 CFR 880.5570</li> </ul>
Product Code	<ul style="list-style-type: none"> <li>- FMF</li> <li>- FMF</li> <li>- FMI</li> </ul>

	Subject Device 510k No	Predicate Device 510k No	Predicate Device Manufacturer
Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock	K201284	K190002	Shanghai Kohope Medical Devices Co., Ltd
Sterile Insulin Syringe for Single use, with needle	K201284	K190002	Shanghai Kohope Medical Devices Co., Ltd
Sterile Hypodermic needle for Single use	K201284	K190002	Shanghai Kohope Medical Devices Co., Ltd

Device Description

Table 5.1. Device Description Summary for Hypodermic Syringe

ITEM	Subject Device
Product name	Sterile Hypodermic Syringe for Single use, 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	64-182mm
diameter	6,6mm-31,6mm
tip type	luer/ luer lock/catheter/perfusion
needle tip configuration	Back bevel needle
nozzle type	Luer / Lock, %6 conical, 1,2 mm
barrel marking specs	0,05ml-1ml
graduation legibility	Legible
needle cover dimensions	L: 35-55mm, D: 6-9mm
needle cover color	Transparent
lubricant composition	Silicone
barrel transparency	Transparent/ UV resistant/ opaque
needlecover strength	min. 2N max. 20N
hub/ needle bond strength	min. 22-69N
Product performance	Complied with ISO 7886-1, ISO 7864, ISO 9626
Volume	2ml, 2,5ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 24ml, 50ml and 60 ml
Sizes	14G,15G,16G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G
Needle Lengths	4–50 mm
Piston material	Isoprene Rubber
Barrel material	PP
Plunger material	PP/PE
Needle material	PP, SUS304
SAL	10 <sup>-6</sup>
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

ITEM	Subject Device
Product name	Sterile Insulin Syringe for Single use, with needle
Indications for use	<p>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.</p> <p>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.</p>
Configuration	Needle Cap, Needle, Piston, Plunger, Barrel, End Cap
Sterility condition	EO Sterilized
Environment of use	Prescription use
Intended users	Patient 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	0.3ml, 0.5ml, 1ml volumes with fixed needle
Needle Lengths	8mm, 13mm
Piston material	Isoprene Rubber
Barrel material	PP
Plunger material	PP
Needle material	SUS304
Needle Cap material	PP
End Cap material	PP
SAL	10 <sup>-6</sup>
Endotoxin Limit	20 EU per device
Biocompatibility	Complied with ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Subchronic Toxicity, Hemolytical effect)



Table 5.3. Device Description Summary for Needle

ITEM	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
Single use	Yes
Operation mode	For Manual Use Only, For Single Use only
Product performance	Complied with ISO 7864, ISO 9626
Sizes	14G,15G,16G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G
Needle Lengths	4–50 mm
Protective cap material	PP
Adhesive material	Epoxy resin
Needle Hub material	PP
Needle material	SUS304
SAL material	10 <sup>-6</sup>
Endotoxin Limit material	20 EU per device
Biocompatibility	Complied with ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Hemolytical effect)

### Technological Characteristics

Table 5.4 Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock Predicate Comparison

Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock			
ITEM	Subject Device	Predicate Device K190002	Comparison
Product name	Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock	Sterile Hypodermic Syringe for Single use, with/without needle	Similar
Product code	FMF	FMF	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same

<b>Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock</b>			
<b>ITEM</b>	<b>Subject Device</b>	<b>Predicate Device K190002</b>	<b>Comparison</b>
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.	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.	Same
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	2ml, 2.5ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 24ml, 50ml	1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml and 60 ml	<b>Difference 1</b>
Sizes	14G,15G,16G,18G,19G,20G, 21G,22G,23G,24G,25G,26G,27G, 28G,29G,30G	18G,19G,20G,21G,22G,23G, 24G,25G,26G,27G,28G,29G, 30G	<b>Difference 2</b>
Needle Lengths	4–50 mm	4–38 mm	<b>Difference 3</b>
<b>Patient contact component and material</b>			
Piston	Isoprene Rubber	Isoprene Rubber	Same
Barrel	PP	PP	Same
Plunger	PP/PE	PP	<b>Difference 4</b>
Needle	PP, SUS304	PP, SUS304	Same
<b>Sterilization</b>			

Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock			
ITEM	Subject Device	Predicate Device K190002	Comparison
SAL	10 <sup>-6</sup>	10 <sup>-6</sup>	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Table 5.5. Sterile Insulin Syringe for Single use, with needle Predicate Comparison

Sterile Insulin Syringe for Single use, with needle			
ITEM	Subject Device	Predicate Device K190002	Comparison
Product name	Sterile Insulin Syringe for Single use, with needle	Sterile Insulin Syringe for Single use, with needle	Same
Product code	FMF	FMF	Same
Regulation No.	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	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and	Same

Sterile Insulin Syringe for Single use, with needle			
ITEM	Subject Device	Predicate Device K190002	Comparison
	expel the fluids through the connector to the patient.	expel the fluids through the connector to the 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	0.3ml, 0.5ml, 1ml volumes with fixed needle	0.3ml, 0.5ml, 1ml volumes with fixed needle	Same
Needle Lengths	8mm, 13mm	8mm, 13mm	Same
Patient contact component and material			
Piston	Isoprene Rubber	Isoprene Rubber	Same
Barrel	PP	PP	Same
Plunger	PP	PP	Same
Needle	SUS304	SUS304	Same
Needle Cap	PP	PP	Same
End Cap	PP	PP	Same
Sterilization			
SAL	10 <sup>-6</sup>	10 <sup>-6</sup>	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Table 5.6. Sterile Hypodermic needle for Single use Predicate Comparison

Sterile Hypodermic needle for Single use			
ITEM	Subject Device	Predicate Device K190002	Comparison
Product name	Sterile Hypodermic needle for Single use	Sterile Hypodermic needle for Single use	Same
Product code	FMI	FMI	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	
Class	II	II	Same
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.	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	Same

<b>Sterile Hypodermic needle for Single use</b>			
<b>ITEM</b>	<b>Subject Device</b>	<b>Predicate Device K190002</b>	<b>Comparison</b>
Configuration	Protective cap Needle Adhesives Needle hub	Protective cap Needle Adhesives Needle hub	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	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	Same
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Product performance	Complied with: ISO 7864 ISO 9626	Complied with: ISO 7864 ISO 9626	Same
Sizes	14G,15G,16G,18G,19G,20G,21G,22G,23G, 24G,25G,26G,27G,28G,29G,30G	18G,19G,20G,21G,22G,23G, 24G,25G,26G,27G,28G,29G,30G	<b>Difference 1</b>
Needle Lengths	4–50 mm	4 – 38 mm	<b>Difference 2</b>
<b>Patient contact component and material</b>			
Protective cap	PP	PP	Same
Adhesive	Epoxy resin	Epoxy resin	Same
Needle Hub	PP	PP	Same
Needle	SUS304	SUS304	Same
<b>Sterilization</b>			
SAL	10 <sup>-6</sup>	10 <sup>-6</sup>	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

## Substantial Equivalence Discussion

### Hypodermic Syringe Discussion

The indications for use statement for the hypodermic syringe subject device is 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, and plunger material.

- **Difference 1:** The subject device includes different syringe volumes compared to the predicate. The subject device includes 2ml, 2.5ml, 12ml and 24 ml volume syringes while the predicate does not include these sizes. The predicate device includes 1 ml, 30 ml, 35 ml 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 of 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 includes additional needle gauges compared to the predicate. The subject device includes larger needle gauges, including 14G, 15G, and 16G. 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 subject device includes additional needle lengths compared to the predicate. The subject device includes the following additional needle lengths: 39 mm – 50 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.
- **Difference 4:** The plunger material of the subject device is PP/PE, while the predicate device plunger 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.

### Insulin Syringe 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. 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.

### 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 1:** The subject device includes additional needle gauges compared to the predicate. The subject device includes larger needle gauges, including 14G, 15G, and 16G. 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 2:** The subject device includes additional needle lengths compared to the predicate. The subject device includes the following additional needle lengths: 39 mm – 50 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.

The intended use, principle of operation, materials, 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.

### Performance Testing

The sterile, single lumen hypodermic needles 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 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, single lumen 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 "Tissue/Bone/Dentin". 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) and pyrogenicity (European Pharmacopoeia 9.0 (2.6.8)) were carried out for the device in question.

The sterile, insulin syringe 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 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 "Tissue/Bone/Dentin". 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) and pyrogenicity (European Pharmacopoeia 9.0 (2.6.8)) were carried out for the device in question.

The sterile, 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, 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 "Tissue/Bone/Dentin". 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) and pyrogenicity (European Pharmacopoeia 9.0 (2.6.8)) were carried out for the device in question.

## 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.