DLP Medical Products, Corp.
Luis Ernesto Paniagua
Director of Operations
203 S. St. Mary's St., Suite 160
San Antonio, Texas 78205

February 9, 2023

Re: K203211
Trade/Device Name: Insulin syringe with integrated needle DL
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 2, 2023
Received: February 2, 2023

Dear Luis Ernesto Paniagua:

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,

Alan M. Stevens -S3

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)*
K203211

Device Name
Insulin syringe with integrated needle DL®

Indications for Use *(Describe)*
Disposable syringe for insulin administration, for the patient with diabetes.

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
PRAStaff@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

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

(1) Date of preparation: January 20th, 2023

(2) Submitter:

DLP Medical Products, Corp.
203 S. St. Mary´s St., Suite 160 San
Antonio Texas 78205 USA.
Luis Ernesto De La Puente Paniagua,
Operations Director
+525543306265
ledelapuente@corporativodl.com.mx

(3) Identification of the proposed device
Insulin syringe with integrated needle DL®.

(4) Proposed Device

Trade name of the product:	Insulin syringe with integrated needle DL®.
Classification:	Disposable sterile plastic syringe with needle Class II
Regulation No:	21 CFR 880.5860
Product code:	FMF- Pistón siringe
Review panel:	General Hospital

(5) Predicate Device

K162180	Disposable Insulin Syringe

(6) Description of the medical device.

Insulin syringe with integrated extra thin stainless-steel needle and dead space less than 0.005 mL, made of medical grade plastic, sterile, disposable, pyrogen free and non-toxic. Sterilized by ethylene oxide.
The product is composed of the following parts:
Cylinder or barrel. Part of the syringe or flange that serves to support the user's fingers and prevent them from slipping when the plunger is operated inside the cylinder or barrel, at one end it allows the entry of a piston and at the opposite end it is reduced in a conical shape forming the pivot. It has enough clarity to allow to see the dosage without difficulty and to identify possible occluded bubbles in the liquid to transfuse.

Piston. Rubber portion that has two rings, one upper and one lower, which serves as an adjustment or hermetic seal against the walls of the cylinder or barrel. The piston does not disassemble during normal syringe use and slides easily into the cylinder or barrel.
Plunger. The piston rod or guide, which is operated inside the cylinder or barrel, has a protrusion at the distal end with a finish that prevents the user's finger from slipping when operating the plunger inside the cylinder or barrel. At the opposite end, a piston is assembled.
Needle. Puncture device used attached to the syringe for the introduction or extraction of the liquid into the human body. May have a medical grade silicone coating.
Needle cover or protector. Medical grade plastic piece with a design to perfectly cover the needle protecting the edge and avoiding accidental punctures.

(7) Indications for use:
Disposable syringe for insulin administration, for the patient with diabetes.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Presentations to be marketed. See Table 1.

Table 1

	Syringe volume	Needle gauge	Needle length	Graduated scale
Insulin syringe with integrated needle DLPJECT®.	1 mL, 0.5 mL y 0.3 mL	30G, 31G y 32G.	4 mm, 6 mm, 8 mm y 13 mm	0 a 30 units. 0 a 50 units. 0 a 100 units.

The product needle: **Insulin syringe with integrated needle DL®,** conforms to the attributes set out in ISO 7864-1:2016.

With regard to the product "Insulin syringe with integrated needle DL®", conform to the attributes set out in ISO 8537:2016: "Sterile single-use syringes, with or without needle, for insulin".

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Table 2

#	Tests	Specifications "Insulin syringe with integrated needle DLPJECT®".
1	Product designation	Insulin syringe with integrated needle. Syringe type 7. Capacity: 0.3 mL, 0.5 mL and 1 mL. Sterile and disposable.
2	Product description	Medical use article, disposable, sterile, pyrogen free, made with non-toxic and non-reactive tissue materials. The article must be sterile, non-toxic pyrogen free and non-reactive tissue. Must be free of dust and/or waste materials. Surfaces that come into contact with the administered liquids or with the patient's tissues must not be able to release particles or contain substances that could dissolve or cause reactions with them. The product is composed of the following parts: Cylinder or barrel, with needle integrated into the body, piston, plunger, needle and needle cover or protector.
		Cylinder or barrel with needle integrated into the body. Part of the syringe or flange that serves to support the user's fingers and prevent them from slipping when the plunger is operated inside the cylinder or barrel, at one end it allows the entry of a piston and at the opposite end the needle is integrated. It has enough clarity to allow to see the dosage without difficulty and to identify possible occluded bubbles in the liquid to be transferred. The interior of the cylinder or barrel is lubricated with medical grade silicone, which should not be observed in the form of drops. The pivoted cylinder or barrel must have a minimum length of 79 mm. The cylinder or barrel must have a graduated scale in insulin units, the scale must have a minimum length of 57 mm. Graduation lines must be located at a right angle to the longitudinal axis of the barrel or cylinder.
		Graduation lines. The graduation lines should be longer when they mark the zero of the scale and every five lines, the intermediate lines should be approximately half the length of the first one. The zero must start at the perimeter of the largest diameter of the cylinder, at the end that has the reduction. Adjacent to the longest graduation lines, they must have the corresponding number, (10,20,30,40,50 60, 70, 80 90 and 100 U.I). At the end of the scale it must have adjacent to the number that indicates the value of the last graduation line, an " U.I.", which indicates that it is insulin units. Similarly, the text U-100 must be mentioned. At the end of the scale should be printed the abbreviation mL or ml, the total capacity of the syringe in mL and the symbol of not reusing. The height of the numbers must not be less than 3 mm. Graduation lines, numbers and units must be clearly defined, be uniformly thick between 0.2 and 0.4 mm, you are placed in planes perpendicular to the barrel axis, the scale and scale numbers must be readable and of a color that clearly contrasts with the syringe.
		Plunger. The piston rod or guide, which is operated inside the cylinder or barrel, has a protrusion at the distal end with a finish that prevents the user's finger from slipping when operating the piston inside the cylinder or barrel. At the opposite end, the piston is assembled. The plunger including the piston should be 88 x 2 mm in length.
		Needle. Puncture device that is used with a tube fixed to the syringe for the introduction of liquid to the human body. May have a medical grade silicone coating.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

		Needle cover or protector. Medical grade plastic piece with a design to perfectly cover the needle protecting the edge and avoiding accidental punctures.		
3	Finish	The parts that make up the product must be free of defects such as internal burrs, external burrs, bubbles, perforations, fractures, roughness, deformations, sharp parts and non-uniform thickness. In all cases the assembly with the hypodermic needle must be firm and not separated by the action of normal use of the article.		
4	**Dimensions**			
	Volume or nominal capacity in mL/cc	0.3	0.5	1.0
	Scale division in ml	5 U.I.	5 U.I.	5 U.I.
	Scale subdivision in ml	1 U.I.	1 U.I.	2 U.I.
	Minimum length of the scale in mm, up to the nominal capacity line	41.0	43.0	57.0
	Maximum silicone mass in mg	If the inner surfaces of the syringe, including the plunger piston, are lubricated, the lubricant will not form fluid droplets on the inside surface of the syringe.		
	Scale tolerance. When the reference line coincides with any line on the scale that is greater than 50% of the nominal capacity, the percentage tolerance is set to:	± 5%	± 4%	± 4%
5	Scale numbering	0.5 units	1.0 units	2.0 units
6	Scale position	When the syringe is held vertically, the ends of all similarly long graduation lines will align vertically with the barrel axis and with each other, within a tolerance of + 0.5 mm.		
7	Characteristics of the cylinder or barrel	Part of the syringe with an eyebrow or flange that serves to support the user's fingers and prevent them from slipping when the plunger is operated inside the cylinder or barrel, at one end it allows the entry of a piston and at the opposite end the needle is integrated. It has enough clarity to allow the user to see the dosage without difficulty and to identify possible occluded bubbles in the liquid to be transferred. The interior of the cylinder or barrel is lubricated with medical grade silicone, which should not be observed in the form of drops. The length of the barrel is such that the syringe has a useful capacity of no less than 10% more than the nominal capacity or 3 mm of plunger travel beyond the scale mark,		

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

		whichever is less.		
8	Flange	The end of the barrel or cylinder is fitted with a finger flange, which ensures that the syringe does not rotate more than 180º when placed on a flat surface and with the scale facing upwards, at an angle of 10º degrees from the horizontal.		
9	Plunger and piston features	The design of the plunger and plunger head is such that when the barrel or cylinder is held with one hand, the plunger can be pushed by the thumb of that hand The plunger head has grooves or other configuration such that it prevents the user's finger from slipping during injection.		
10	Reference line	There is a defined and clearly visible edge at the end of the piston that serves as a reference line to determine the capacity corresponding to any reading on the syringe scale. This line is in contact with the inner surface of the barrel or cylinder. This is verified immediately.		
11	Dead space	The volume of liquid contained in the barrel or cylinder and in the pivot when the piston is fully inserted complies with maximum 0.005 mL.		
12	**Hypodermic Needle (Dimensions)**			
	Gauge (G)	30	31	32
	Nominal external diameter (mm)	0.298-0.320	0.254-0.266	0.229-0.241
	Minimum nominal inner diameter (mm)	0.133	0.114	0.089
	Useful length	Needle length tolerance should be within ± 1.25 mm.		
	Primary angle	9° a 11°		
	Color code	The colors used to identify the concentration of insulin will be as follows Orange for U-100		
13	Cannula adhesion (N)	The minimum joint resistance of the needle tube with nominal external diameter less than 0.33 should be 11 N.		
14	Hermeticity	None of the syringes should leak.		
15	Systemic injection	MGA-DM 3083. Passes the Test.		
16	Intracutaneous reactivity	MGA-DM 3071. Passes the Test.		
17	Pyrogens	MGA 0711. This determination can also be carried out with the MGA 0316 method, Bacterial Endotoxins. In both cases it satisfies the test method.		
18	Sterility	MGA 0381. Passes the Test.		
19	Ethylene oxide residues	Complies with ISO 10993-7:2008, 4 mg maximum/24h		
20	Acidity or alkalinity	MGA-DM 0001, Method II, Test compliance		
21	Removable metal limit	MGA 0331. The sample extract shall not contain in total more than 5 mg/L of lead, tin, zinc and iron. The cadmium content in the extract will be less than 0.1 mg/L.		
22	Product marking	The marking on the syringe must be in clear, legible and permanent characters during use, and includes the following: name, company name or		

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

		symbol of the manufacturer, nominal capacity in cm^3 or ml and single graduated scale.
23	Label and counter-label NOM-137-SSA1-2008	Complies with NOM-137-SSA1-2008, Medical Device Labeling.
24	Labeling of the primary Packaging / RIS health supplies regulation	Complies with the provisions of the Regulation of Inputs for Health. Second section. Labeling and packaging.

Biocompatibility.

The product meets the following biocompatibility tests. See Table 3.

Table 3

Tests	Methodology	Specifications	Result
Cytotoxicity (elution)	According to ISO 10993, Biological Evaluation of medical devices. Part 5: Test for in vitro cytotoxicity.	Reactivity grade: 0 – 2	Reactivity grade: 0 None Discrete intracytoplasmic granules, without cell lysis. Not cytotoxic
Cytotoxicity (agar diffusion)	According to ISO 10993, Biological Evaluation of medical devices. Part 5: Test for in vitro cytotoxicity.	Reactivity grade: 0 – 2	Reactivity grade: 0 None Undetectable zone around or below the sample. Not cytotoxic
¥ Irritability	In accordance with the International Standard ISO 10993-10:2010, Biological evaluation of medical devices. Part 10: Test for irritation and skin sensitization, pp. 7 – 11.	0 to 0,4: Not measurable 0,5 to 1,9: Slight 2 to 4,9: Moderate 5 to 8: Severe	0,0: Not measurable
¥ Sensitization	In accordance with the International Standard ISO	Grade 0: No visible change	Grade 0: No visible change

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

	10993-10:2010, Biological evaluation of medical devices. Part 10: Test for irritation and skin sensitization, pp.20 – 23.	Grade 1: Slight or irregular erythema Grade 2: Moderate and confluent erythema Grade 3: Intense erythema or swelling	
Systemic Toxicity	According to ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	If during the observation period none of the animals treated with the sample extract exhibits a significantly greater biological reaction than the animals treated with the blank, the sample meets the test requirements.	During the observation period none of the animals treated with the sample extract exhibited a significantly greater biological reaction than the animals treated with the blank, the sample meets the test requirements.
Pyrogens	According to ISO 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	For information only	The sum of the temperature increments of the test animals is 0.26 °C so the sample is considered apyrogenic
Acute toxicity	According to ISO 10993-12:2012. Biological evaluation of medical devices, Part 12: Sample preparation and reference materials.	The saline solution extract of the medical device (insulin syringes) for 72±2h a 37±1°C must not show adverse clinical effects during the acute toxicity study in male Wistar rats.	The saline solution extract of the medical device (insulin syringes) for 72±2h a 37±1°C did not show adverse clinical effects during the acute toxicity study in male Wistar rats.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Subacute toxicity	According to ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	The saline solution extract of the medical device (syringes for insulin) for 72 ± 2 h at 37 ± 1 ºC did not show adverse clinical effects during the subaqueous toxicity study in male and female rats of the Wistar strain.	The saline solution extract of the medical device (syringes for insulin) for 72 ± 2 h at 37 ± 1 ºC did not show adverse clinical effects during the subaqueous toxicity study in male and female rats of the Wistar strain.
Subchronic toxicity	According to ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices Part 11: Tests for systemic toxicity.	The saline solution extract of the medical device (insulin syringes) for 72 ± 2 h at 37 ± 1 °C must not show adverse clinical effects during the subchronic toxicity study in male and female rats of the Wistar strain.	The saline solution extract of the medical device (insulin syringes) for 72 ± 2 h at 37 ± 1 °C did not show adverse clinical effects during the subchronic toxicity study in male and female rats of the Wistar strain.

Sterility

Sterilization method. Sterilization by ethylene oxide.
Meets. ISO 10993-7:2008.
Ethylene oxide residues: < 4 mg / 24 h < 4 mg / 24 h in compliance with ISO 10993-7: 2008.
Ethylenenhydrin residues: < 9 mg / 24 h < 4 mg / 24 h in compliance with ISO 10993-7: 2008.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

(8) Identification of the predicated device

Predicated device: Number 510 (k): K162180
Product name: Disposable Insulin Syringe
Berpu Medical Technology Co., Ltd. (China)

Indication for use

Characteristics	**Proposed Device** "Insulin syringes with integrated needle DLPJECT®"	**Predicate Device** Disposable Insulin Syringe K162180
Indication for use	Disposable syringe for insulin administration, for the patient with diabetes.	The disposable insulin syringe is designed for medical purposes for manual aspiration of Insulin 100 U and for the injection of insulin into parts of the body below the surface of the skin.
Prescription Only or Over the counter	Prescription Use	Prescription Use

The indications for use statement for the subject device is similar to the predicate device.
There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Substantial equivalence

Technological Characteristics

The technological characteristics of the Insulin syringes with integrated needle DLPJECT® are similar to those of the predicate device. A summary of the differences between Insulin syringes with integrated needle DLPJECT® subject device and Disposable Insulin Syringe cleared under K162180 are outlined in table below.

General Information	Subject Device "Insulin syringes with integrated needle DLPJECT®"	Predicate Device: Disposable Insulin Syringe K162180	Comparison
Specific use drug	U-100 Insulins	U-100 Insulins	Same
Single Use Only	Yes	Yes	Same
Non-pyrogenic	Yes	Yes	Same
Sterilization	Ethylene oxide sterilization	Ethylene oxide sterilization	same
SAL10-6	Yes	Yes	Same
Capacity	0.3mL, 0.5mL, 1.0mL	0.3mL, 0.5mL, 1.0mL	Same
Cannula Gauge Size(s)	30G, 31G, 32G	27G, 28G,29G, 30G, 31G	Different see Comment # 1
Mode of operation	Manual use	Manual use	Same

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Bezel	Primary angle: 9° - 11°	Unknow	Different see Comment # 2
Operational Test	ISO 9626:2016 ISO 7864-1:2016. ISO 8537:2016	Complies with: ISO 9626 ISO 7864 ISO 8536 ISO 8537	Similar see Comment # 3
General Information	**Subject Device "Insulin syringes with integrated needle DLPJECT®"**	**Predicate Device: Disposable Insulin Syringe K162180**	**Comparison**
Materials			
Cannula (Needle)	SUS 304 stainless steel tube	Stainless Steel (SUS304)	Same
Protective end cap	Polypropylene RP250	Polypropylene (PP)	Same
Plunger	Polypropylene RP250	Polypropylene (PP)	Same
Barrel	Polypropylene RP250	Polypropylene (PP)	Same
Piston	Poly isoprene rubber	Polyisoprene Rubber	Same
Needle cover	Polypropylene RP250	Polypropylene (PP)	Same

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Protector dye</td><td>Orange concentrate 20342F</td><td>Unknow</td><td rowspan="5">Diferent
In the predicate device, not all components are declared.
See
Comment # 4</td></tr>
<tr><td>Silicone</td><td>Xiameter™ / PMX-200 Silicone Fluid 12500 cst</td><td>Unknow</td></tr>
<tr><td>Scale Marking Ink</td><td>Solvent base ink used for polypropylene printing and SIB polymer resin</td><td>Unknow</td></tr>
<tr><td>Cannula Bonding Adhesive</td><td>Resin polymer 8E-13L</td><td>Unknow</td></tr>
<tr><td>Needle Pavilion</td><td>Polypropylene RP250</td><td>Unknow</td></tr>
<tr><td>Plunger dye</td><td>Master batch white polyethylene base</td><td>Unknow</td><td></td></tr>
<tr><td>Biocompatibility</td><td>
<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Cytotoxicity (elution)</td><td>Reactivity grade:
0
None
Discrete intracytoplasmic granules, without cell lysis.
Not cytotoxic</td></tr>
<tr><td>Cytotoxicity (agar diffusion)</td><td>Reactivity grade:
0
None
Undetectable zone around or below the sample.
Not cytotoxic</td></tr>
<tr><td>¥ Irritability</td><td>0,0: Not measurable</td></tr>
<tr><td>¥ Sensitization</td><td>Grade 0:</td></tr>
</table>
</td><td>
<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Cytotoxicity</td><td>Not cytotoxic</td></tr>
<tr><td>Irritation</td><td>No irritation reactivity</td></tr>
<tr><td></td><td>No significant</td></tr>
</table>
</td><td>Similar.See
Comment # 5</td></tr>
</table>

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

		No visible change		Sensitization	evidence of skin sensitization
	Systemic injection	During the observation period none of the animals treated with the sample extract exhibited a significantly greater biological reaction than the animals treated with the blank, the sample meets the test requirements.		Systemic toxicity	No significant evidence of systemic toxicity
	Pyrogens	The sum of the temperature increments of the test animals is 0.26 °C so the sample is considered apyrogenic		Pyrogens	No evidence of pyrogens
	Sterility	No microbial growth is			

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

		observed during the 14 days of incubation in the MFT or CST media.		
	Acute toxicity	The saline solution extract of the medical device (insulin syringes) for 72±2h a 37±1°C did not show adverse clinical effects during the acute toxicity study in male Wistar rats.		
	Subacute toxicity	The saline solution extract of the medical device (syringes for insulin) for 72 ± 2 h at 37 ± 1 ºC did not show adverse clinical effects during the subaqueous toxicity study in male and female rats of the Wistar strain.		

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

	Subchronic toxicity	The saline solution extract of the medical device (insulin syringes) for 72 ± 2 h at 37 ± 1 °C did not show adverse clinical effects during the subchronic toxicity study in male and female rats of the Wistar strain.		

There are no technological differences between the subject device and the predicate device except for the following: Cannula gauge size, bezel primary angle and some materials which are not declared in predicate device, there are similarities in operational and biocompatibility tests.
The intended use, principle of operation, the main materials, specifications, and sterilization information for the subject device are the same as for the predicate device.

Comment #1: Cannula Gauge Size differences.
The 32 G gauge is not offered in the predicate device and 27 G, 28 G and 29 G gauges are not offered in the proposed device.
The outer diameters of the cannula offered in the proposed device has been evaluated and the test results conforms to requirements the International Standard ISO 9626 (2016): Stainless steel needle tubing for manufacture of medical devices. Requirements and test methods, for this reason, these differences do not raise new questions of safety or effectiveness.

Comment #2: Bezel primary angle differences
In the predicate device the bezel primary angle is not declared however in the proposed device bezel primary angle was evaluated and the test results comply the ISO 7864:2016 Sterile hypodermic needles for single use Requirements and test methods, therefore, the differences on configuration and materials does not affect substantially equivalence.

Comment #3: Operational test similarities
Both products are evaluated with the ISO 9626:2016, ISO 7864-1:2016, and ISO 8537:2016 standards, which demonstrate the functionality of the proposed device.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

This difference does not to affect the Substantially Equivalency (SE) between the proposed and predicate devices since all performance parameters were evaluated and demonstrated results in compliance with the standards.

Comment #4: Differences in some materials

The materials protective dye, cannula, lubrication, scale marking ink, cannula union, adhesive, needle, pavilion, and dye plunger are not declared in the device predicate, so it is a difference between predicate device and subject device.

Based on the risk analysis carried out for the product where the indication for use, user exposure time and the raw materials used for its manufacture were evaluated the biocompatibility tests carried out allow to demonstrate the biological safety of the product.

Some raw materials of Insulin syringes with integrated needle DL® are different from predicate device. however, the biocompatibility for the subject device has been evaluated and the results comply with the requirements of ISO 10993. The differences does not raise new safety and efficacy issues.

Comment #5: Biocompatibility test similarities

The predicated device presented the following tests: Cytotoxicity, Irritation, Sensitization, Systemic toxicity, and Pyrogens. Both products were evaluated with the same biocompatibility tests and both products have similar performance, same exposure, and duration of contact time with the organism.

The biocompatibility tests of the product **Insulin syringes with integrated needle DL®,** has been evaluated and the test results conforms to requirements the *ISO 10993-1, Biological evaluation of medical devices.* These differences does not raise new safety and efficacy issues.

1. Substantial equivalence

Performance Testing:

The Insulin syringes with integrated needle DL® described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

ISO 9626:2016: Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

ISO 7864-1:2016. Sterile hypodermic needles for single use — Requirements and test methods.
ISO 8537:2016. Sterile single-use syringes, with or without needle, for insulin.

Biocompatibility testing

In accordance with ISO 10993-1, the device is classified as: device is classified as externally communicating with prolonged patient contact due to repeated use. The following Testing was conducted:

- Cytotoxicity
- Sensitization
- Irritability
- Acute toxicity
- Pyrogenicity
- Systemic injection
- Subacute and Subchronic Toxicity
- Particulate Testing, USP<788>

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Sterility, Shipping and Shelf-life

•The Insulin syringes with integrated needle DL®"'s sterilization method is Ethylene oxide.

The sterilization method has been validated per ISO 11135-1:2015, which has thereby determined the routine control and monitoring parameters.

•The determinations of pyrogens carried out in accordance with the ISO 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

•Minimum Sterility Assurance Level of 10-6.

•Sterile barrier testing performed on the subject device:

-Microbial Ingress per analytical test procedures.

- Syringe air bubble leak per analytical test procedures.

• Packaging Integrity Testing under simulated shipping conditions were conducted to satisfy the requirements in ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems.

All packaging deemed acceptable for protection of product and sterility maintenance.

Real time stability testing has been conducted to validate the sterility and performance of the Insulin syringes with integrated needle DL®" and is support shelf-life of 5 years.

Clinical Test Summary

No clinical study is included in this submission.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.

Conclusion:

The difference in some materials of components, configuration and sizes have been evaluated through non-clinical testing; the tests are in accordance with those established in the standards, ISO 9626: 2016, ISO 7864-1: 2016, ISO 8537:2016, and ISO 10993.

The differences between the predicate device: Disposable Insulin Syringe (K162180) and the subject device do not raise any new or different questions of safety or effectiveness. Performance testing data demonstrates that the proposed device is substantially equivalent with respect to the indications for use, target populations, and technological characteristics.

203 S. ST. MARY´S ST., SUITE 160 SAN ANTONIO TEXAS 78205 USA.