March 21, 2018

HTL-STREFA S.A.
Aleksandra Prazmowska-Wilanowska
Regulatory Affairs Director
ul. Adamowek 7
95-035 Ozorkow
POLAND

Re: K171982
Trade/Device Name: Droplet® Pen Needles (Models: Droplet® Pen Needles 4mm x 32G, Droplet® Pen Needles 5mm x 32G, Droplet® Pen Needles 6mm x 32G, Droplet® Pen Needles 8mm x 32G, Droplet® Pen Needles 5mm x 31G, Droplet® Pen Needles 6mm x 31G, Droplet® Pen Needles 8mm x 31G, Droplet® Pen Needles 10mm x 29G, Droplet® Pen Needles 12mm x 29G)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 21, 2018
Received: February 21, 2018

Dear Ms. Aleksandra Prazmowska-Wilanowska:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171982

Device Name
Droplet® Pen Needles (Models: Droplet® Pen Needles 4mm x 32G
Droplet® Pen Needles 5mm x 32G
Droplet® Pen Needles 6mm x 32G
Droplet® Pen Needles 8mm x 32G
Droplet® Pen Needles 5mm x 31G
Droplet® Pen Needles 6mm x 31G
Droplet® Pen Needles 8mm x 31G
Droplet® Pen Needles 10mm x 29G
Droplet® Pen Needles 12mm x 29G)

Indications for Use *(Describe)*
Droplet® Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.

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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K171982

510(k) Summary

As required by the Medical Devices Act of 1990 and in accordance with 21 CFR §807.92(a).

Summary

[807.92 (a)(1,2)]

Date Prepared: March 15, 2018

Submitted By:
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Trade Name: Droplet® Pen Needles

Device models:
Droplet® Pen Needles 4 mm x 32G
Droplet® Pen Needles 5 mm x 32G
Droplet® Pen Needles 6 mm x 32G
Droplet® Pen Needles 8 mm x 32G
Droplet® Pen Needles 5 mm x 31G
Droplet® Pen Needles 6 mm x 31G
Droplet® Pen Needles 8 mm x 31G
Droplet® Pen Needles 10 mm x 29G
Droplet® Pen Needles 12 mm x 29G

Common Name: Pen Needle

Regulation Number: 21 CFR § 880.5570

Product Code: FMI

Device Classification: II

Review Panel: 80 General Hospital

Predicate Device

[807.92(a)(3)]

The legally marketed device to which substantial equivalence is claimed is:

Manufacturer	Trade Name	510(k) Number
Becton Dickson & Co.	BD Pen Needle	K162516

Secondary Predicate Device

Manufacturer Name	Trade Name	510(k) Number
HTL-Strefa S.A.	Droplet® Pen Needle	K143437

The secondary predicate device cleared under K143437 has been included in this submission to cover all gages and lengths of the new device. All design features remain unchanged with regard to the device submitted and cleared under K143437.

Description of Device:

[807.92(a)(4)]

The Droplet® Pen Needles are sterile, single use needles intended for use with pen injector devices for the subcutaneous injection of drugs. Pen needles are used by consumers, caregivers and healthcare professionals.

The pen needle assembly consists of a double-ended cannula that is assembled into an injection molded hub using adhesive. The hub has internal threads, which allow it to be screwed onto the pen injector device. This allows the cartridge end of the cannula to penetrate through the rubber septum of the cartridge. The patient end and the cartridge end of the cannula are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.

There is an inner needle shield assembled over the patient end of the cannula to protect the needle point from damage and accidental needle sticks. There is also an outer cover. Each pen needle assembly is protected with a peel away seal to provide a sterility barrier.

Indications for Use:

[807.92(a)(5)]

Droplet® Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.

Technological Characteristics:

[807.92(a)(6)]

A comparison of characteristics of Droplet® Pen Needles, the predicate device and the secondary predicate device is shown in the table below:

Device Comparison between New Device, Predicate Device and the Secondary Predicate Device Including Indications for Use

		New Device	**Predicate Device**	**Secondary Predicate Device**
Manufacturer		HTL-STREFA S.A.	Becton Dickinson	HTL-STREFA S.A.
510(k) Number		K171982	K162516	K143437
Product Code		FMI	FMI	FMI
Design	*Primary Container*			
	Needle Shield			
	Needle Tube and Hub			
Indications for Use		The Droplet® Pen Needle is intended for use with a pen injector device for the subcutaneous injection of drugs.	BD Pen Needle is intended for use with a pen injector device for the subcutaneous injection of drugs.	The Droplet® Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin.
Principle of operation		Manual	Manual	Manual
Method of attachment to pen injector		Screw threads	Screw threads	Screw threads

Length	4mm, 5mm, 6mm, 8mm, 10mm, 12mm	4mm, 5mm, 8mm, 12.7mm	4mm, 5mm, 6mm, 8mm, 10mm, 12mm
Gage	29G, 31G, 32G	29G, 30G, 31G, 32G	29G, 31G, 32G
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Conforms to ISO 10993-1
Sterility	SAL = 10^{-6}	SAL = 10^{-6}	SAL = 10^{-6}
Sterilization method	Gamma irradiation	Gamma irradiation	Gamma irradiation
Shelf Life	5 years	5 years	3 years
Unit Packaging	Polypropylene container with seal made of medical grade paper	Polypropylene container with seal made of medical grade paper	Polypropylene container with seal made of medical grade paper
User Packaging	Cardboard sales box	Cardboard sales box	Cardboard sales box
Materials			
• *Needle Tube*	Medical Grade Stainless Steel	Medical Grade Stainless Steel	Medical Grade Stainless Steel
• *Hub, Primary Container, Needle Shield*	Plastic resins	Plastic resins	Plastic resins
• *Lubricant*	Medical grade silicone	Medical grade silicone	Medical grade silicone

The new device, the predicate device and the secondary predicate device are classified under 21 CFR 880.5570, which states: "A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin."

There are no significant differences in the design, principle of operation, method of attachment to pen injector, biocompatibility, sterilization method, materials, or intended use between the Droplet® pen needle device and the predicate device.

The Droplet® pen needle differs from the predicate device as follows:

1. The Droplet® pen needle has slightly different molded features of its primary container, needle shield, and hub.
2. The Droplet® pen needle product line does not include a 30G model.
3. The Droplet® pen needle product line includes an additional model with a 6 mm needle length.
4. The Droplet® pen needle product line's longest needle length is 12 mm, while the predicate's longest needle length is 12.7 mm.

There are no significant differences in the design, principle of operation, method of attachment to pen injector, biocompatibility, sterilization method, materials, or intended use between the Droplet® pen needle device and the secondary predicate device.

The Droplet® pen needle differs from the secondary predicate device as follows:

1. In the indications for use – the clarification to the intended use of the Droplet® pen needle does not introduce critical differences or new risks to the intended use of the device.

The differences do not raise new questions of safety or effectiveness for the subject device. Droplet® pen needle product line and the predicate products line cover a substantially equivalent range of options in gage and needle lengths and the few specific differences between the product lines do not have any impact on performance.

Based upon the above comparisons to the predicate device, Droplet® Pen Needles are substantially equivalent to the predicate device.

Non-Clinical Performance Data:

[(807.92(b)(1)]

Droplet® pen needles successfully passed all the required non-clinical testing which included the following:

- Testing for compliance with the requirements of 11608-2:2012 *Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles*

Test Parameter	Requirement – ISO 11608-2:2012	Result
Materials	The needle shall be made of tubing materials specified in ISO 9626.	**Requirement met**
Dimensions	The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2.	**Requirement met**
Determination of flow rate through the needle (not required by the standard)	The needle was tested in accordance with Annex A to ISO 11608-2 to determine flow rate through the needle.	**Requirement met**
Bond between hub and needle tube	The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	**Requirement met**
Freedom from defects	The needle tube shall fulfill the requirements of ISO 7864, clause11.3.	**Requirement met**
Lubrication	The needle tube should be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside surface of the needle tube.	**Requirement met**

Dislocation of measuring point at patient end	Dislocation of the cannula point at the patient end shall be in accordance with Table 2 when tested in accordance with Clause 8 (of ISO 11608-2).	**Requirement met**
Determination of functional compatibility with needle-based injection systems	Compatibility with any NIS (Needle-based Injection System) shall be claimed only after testing in accordance with Clause 11.	**Requirement met**
Ease of assembly and disassembly	Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11.	**Requirement met**
Pre-conditioning of needles	All requirements of the standard related to preconditioning of needles were met.	**Requirement met**

- **Biocompatibility testing:**

Biocompatibility Test Summary – no adverse biocompatibility effects were observed:

Test method	Compliance with	Result
Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5 - Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity	The test article showed no evidence of causing cell lysis or toxicity.
ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
ISO Intracutaneous Study in Rabbits	ISO 10993-10 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	The test article met the requirements of the test.
ASTM Hemolysis Study	ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4 - Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood	Both the test article in direct contact with blood and the test article extract were non-hemolytic.
ISO Two Week Toxicity Study in the Rat, Repeated Parenteral Administration of Two Extracts	ISO 10993-11 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	There were no microscopic changes considered to be a test article related response. Parenteral administration of the test article extract did not produce systemic toxicity in rats.
ISO Systemic Toxicity Study in Mice	ISO 10993-11 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article met the requirements of the study.

Test method	Compliance with	Result
USP Rabbit Pyrogen Study, Material-mediated	ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	The total rise of rabbit temperatures during the 3 hour observation period was within acceptable USP limits. The test article was judged as non-pyrogenic.
USP Pyrogen Study - Material Mediated	USP, General Chapter <151>, Pyrogen Test as recommended by ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	The test article was judged as nonpyrogenic.

Clinical Performance Data:

[(807.92(b)(2)]

Clinical data is not required.

Conclusion:

[(807.92(b)(3)]

Droplet® Pen Needles are concluded to be substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate device.