October 15, 2020

HTL-Strefa S.A.
Aleksandra Prazmowska-Wilanowska
QA/RA Director
Adamowek 7
Ozorkow, 95-035
Poland

Re: K202340
Trade/Device Name: Droplet Pen Needle 30G & 33G
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 4, 2020
Received: August 17, 2020

Dear 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. 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,

For CPT Alan 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202340

Device Name
Droplet Pen needle 30G &33G

Indications for Use *(Describe)*
The DROPLET PEN NEEDLES 30G & 33G 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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510(k) Summary K202340

Date Prepared:	October, 7th, 2020
Submitted By:	HTL-STREFA S.A. ul. Adamówek 7 95-035 Ozorków POLAND
Primary Contact:	Aleksandra Prażmowska-Wilanowska RA Director Phone: +48 42 270 00 16 ola.prazmowska-wilanowska@htl-strefa.pl
Secondary Contact:	Izabela Banaś Senior RA Specialist Phone: +48 42 270 02 93 izabela.banas@htl-strefa.pl
Trade Name:	DROPLET® PEN NEEDLE 30G & 33G
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:

Predicate device:

Manufacturer Name	Trade Name	510(k) Number
HTL-Strefa S.A.	Droplet pen needle 34G	K192082

Description of Device:

[807.92(a)(4)]

DROPLET® PEN NEEDLES 30G & 33G 4G are sterile, single use needles intended for use with pen injector devices for the subcutaneous injection of drugs. The pen needles are OTC devices.

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)]

The DROPLET® PEN NEEDLES 30G & 33G are intended for use with pen injector devices for the subcutaneous injection of drugs.

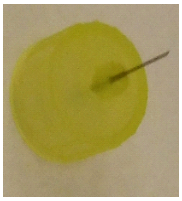
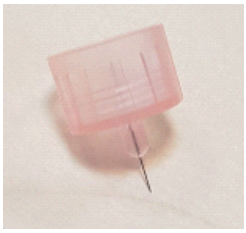
Technological Characteristics:

[807.92(a)(6)]

A comparison of characteristics of DROPLET® PEN NEEDLE 30G, 33G and the predicate device is shown in the table below:

Device Comparison between Subject Device and Predicate Device Including Indications for Use

Feature	Subject Device DROPLET® PEN NEEDLE 30G	Subject Device DROPLET® PEN NEEDLE 33G	Predicate Device DROPLET® PEN NEEDLE 34G	Conclusion
510(k) Number	K202340	K202340	K192082	
Product Code	FMI	FMI	FMI	Same

Feature		Subject Device DROPLET® PEN NEEDLE 30G	Subject Device DROPLET® PEN NEEDLE 33G	Predicate Device DROPLET® PEN NEEDLE 34G	Conclusion
Design	*Primary Container*				Same
	Needle Shield				Same
	Needle Tube and Hub				Different No impact on safety or effective
Indications for use		The DROPLET® PEN NEEDLE 30G is intended for use with a pen injector device for the subcutaneous injection of	The DROPLET® PEN NEEDLE 33G is intended for use with a pen injector device for the subcutaneous injection of	The DROPLET® PEN NEEDLE 34G is intended for use with a pen injector device for the subcutaneous injection of	Same
Length		8 mm	4 mm	3.5 mm	Different No impact on safety
Gage		30G	33G	34G	Different No impact on safety
Method of attachment to pen injector		Screw threads	Screw threads	Screw threads	Same

Feature	Subject Device DROPLET® PEN NEEDLE 30G	Subject Device DROPLET® PEN NEEDLE 33G	Predicate Device DROPLET® PEN NEEDLE 34G	Conclusion
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Same
Sterility	SAL = 10^{-6}	SAL = 10^{-6}	SAL = 10^{-6}	Same
Sterilization method	EtO	EtO	EtO	Same
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	Same
User Packaging	Cardboard sales box	Cardboard sales box	Cardboard sales box	Substantially equivalent
Materials				
Needle Tube	Stainless steel AISI 304L	Stainless steel AISI 304L	Stainless steel AISI 304L	Same
Hub Primary Container Needle Shield	Plastic resins	Plastic resins	Plastic resins	Same
Lubricant	Medical grade silicone	Medical grade silicone	Medical grade silicone	Same

HTL-STREFA S.A. has determined that the Droplet® Pen Needle 30G & 33G is substantially equivalent to a predicate device currently cleared for marketing in the United States.

The subject device and the 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."

The Droplet® Pen Needle 30G&33G is substantially equivalent to the Droplet® Pen Needle 34G cleared under K192082 in terms of indications for use, compositions, material, design and performance. Specifically, the following performance comparisons were made to determine equivalence to the predicate device pen needles referenced: length, gauge, biocompatibility,

materials, shelf life and sterility. Based on the comparisons above of the predicate devices the Droplet® Pen Needle 30G & 34G has raised no different questions of safety and effectiveness.

The difference in needle hub color between the proposed device and the predicate device – 30G x 8 mm and 33G x 4 mm vs. 34G x 3.5 mm has been analyzed. The different colored hubs were introduced for easy needle size identification (color coding for the user). The hubs, irrespective of their color, are made of the same raw materials and were assessed with regard to biocompatibility. No negative biological reaction is expected to occur as a result of the different color. Consequently, the hub color is considered not to have any impact on safety or performance of the proposed device.

The difference in needle gage and length between the proposed device and the predicate device – 30G x 8 mm and 33G x 4 mm vs. 34G x 3.5 mm has also been analyzed. Based on all available design, technical and technological information as well as the published scientific and clinical data and based on information on pen needles by other manufacturers available in the USA, we have concluded that the two proposed needle gages and lengths ensure the same level of confidence for device safety and performance with regard to ensuring subcutaneous injection. They are being introduced to meet individual needs of patients based on their skin type, BMI, and drug dosing and treatments.

Based on the above analysis of the needle length, it has been concluded that difference in needle gage or length between the Droplet 30G & 33G and the Droplet 34G device does not impact safety or performance of the former device and raises no different questions of safety and performance.

The proposed device and the 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."

The subject device and the predicate device use statements similar to the underlined portion of the excerpt from the regulation.

HTL-STREFA S.A. has determined that the Droplet® Pen Needle 30G and 33G is substantially equivalent to a predicate device currently cleared for marketing in the United States.

Non-Clinical Performance Data:

[(807.92(b)(1)]

DROPLET® PEN NEEDLE 30G & 33G 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*

- The table below presents the requirements of the 11608-2:2012 *Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles* standard and the result of the testing conducted.

Test Parameter	Clause no. & requirement of ISO 11608-2:2012	Result
Materials	**4.1** The needle shall be made of tubing materials specified in ISO 9626.	Meets requirements
Dimensions	**4.2** The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2.	Meets requirements
Determination of flow rate through the needle	**4.3** The needle was tested in accordance with Annex A to ISO 11608-2 to determine flow rate through the needle.	Meets requirements
Bond between hub and needle tube	**4.4** The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	Meets requirements
Needle points	**4.5** When examined under a magnification of x2,5, needle points shall appear sharp and free from feather edges, burrs and hooks.	Meets requirements
Freedom from defects	**4.6** The needle tube shall fulfill the requirements of ISO 7864, 11.3.	Meets requirements
Lubrication	**4.7** 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.	Meets requirements
Dislocation of measuring point at patient end	**4.8** Dislocation of the cannula point at the patient end shall be in accordance with Table 2 below when tested as per Clause 8 (of ISO 11608-2).	Meets requirements
Determination of functional compatibility with needle-based injection systems	**4.9** Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11.	Meets requirements
Ease of assembly and disassembly	**4.10** 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.	Meets requirements
Sterility	**4.11** The needle in its unit packaging shall has been subjected to a validated sterilization process.	Meets requirements
Pre-conditioning of needles	**6** All requirements of the standard related to preconditioning of needles were met.	Meets requirements

Biocompatibility testing:

Selection of Biological Evaluation Tests

The Biological Tests selected to be performed on the sterile final product that has direct contact with the end-user according to the 2016 FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" considering contact type and duration were as follows:

1. Cytotoxicity
2. Sensitization
3. Irritation or Intracutaneous Reactivity
4. Acute Systemic Toxicity
5. ISO Two Week Systemic Toxicity Study in the Rat, Repeated Parenteral Administration of Two Extracts
6. Material-Mediated Pyrogenicity
7. Hemocompatibility

Biocompatibility tests selected as per the requirements of 2016 FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" considering contact type and duration for the DROPLET® PEN NEEDLE 30G & 33G did not show any adverse biological / biocompatibility reactions.

Clinical Performance Data:

[(807.92(b)(2)]

Clinical data is not required.

Conclusion:

[(807.92(b)(3)]

DROPLET® PEN NEEDLE 30G & 33G concluded to be substantially equivalent in the intended use, technology/principle of operation, materials and performance to the legally market predicate device.