April 21, 2020

HTL-Strefa S.A
Aleksandra Prazmowska-Wilanowska
Regulatory Affairs Director
Adamowek 7
Ozorkow, 95-035 Pl

Re: K192082
Trade/Device Name: Droplet Pen Needle 34G
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 20, 2020
Received: March 23, 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 CAPT Alan Stevens
Assistant 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)*
K192082

Device Name
DROPLET PEN NEEDLE 34G

Indications for Use *(Describe)*
The DROPLET® PEN NEEDLE 34G is 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.

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510(k) Summary

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

Summary

[807.92 (a)(1,2)]

Date Prepared:	March 20, 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 34G
Common Name:	Pen Needle
Regulation Number:	21 CFR § 880.5570
Regulation Name	Needle, Hypodermic, Single Lumen

Product Code: FMI

Device Classification: II

Review Panel: 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
Terumo Medical Corporation	Terumo® Pen Injector Needle 34	K140516

Reference device:

Manufacturer Name	Trade Name	510(k) Number
HTL-Strefa S.A.	DROPLET® PEN NEEDLE	K171982

The reference device cleared under K171982 has been included in this submission to cover the indications for use of the subject device.

Description of Device:

[807.92(a)(4)]

DROPLET® PEN NEEDLES 34G 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 siliconebased 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 34G 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 34G, the predicate device and the reference device is shown in the table below:

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

Feature	Subject Device DROPLET® PEN NEEDLE 34G	Predicate Device Terumo® Pen Injector Needle 34	Reference Device DROPLET® PEN NEEDLE	Conclusion
510(k) Number	pending	K140516	K171982	n/a
Product Code	FMI	FMI	FMI	Same
Design	Primary Container			Same
	Needle Shield			Same
	Needle Tube and Hub			Same
Indications for use	The DROPLET® PEN NEEDLE 34G is intended for use with a pen injector device for the subcutaneous injection of drugs.	The Terumo® Pen Injector Needle 34 is intended for use with a pen injector device for the subcutaneous injection of drugs, including insulin.	The Droplet® Pen Needle is intended for use with a pen injector device for the subcutaneous injection of drugs.	Similar to predicate Same as reference
Length	3.5mm -0.4mm +0.5mm	4mm ±1.25mm	12 mm, 10 mm, 8 mm, 6mm, 5 mm, 4mm	See Discussion

Feature	Subject Device DROPLET® PEN NEEDLE 34G	Predicate Device Terumo® Pen Injector Needle 34	Reference Device DROPLET® PEN NEEDLE	Conclusion
Gage	34G	34G	29G, 30G, 31G, 32G	Same as predicate
Method of attachment to pen injector	Screw threads	Screw threads	Screw threads	Same
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	E-beam radiation	Gamma irradiation	See Discussion
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	See Discussion
User Packaging	Cardboard sales box	Cardboard sales box	Cardboard sales box	See Discussion

Feature	Subject Device DROPLET® PEN NEEDLE 34G	Predicate Device Terumo® Pen Injector Needle 34	Reference Device DROPLET® PEN NEEDLE	Conclusion
Materials				
Needle Tube	Stainless steel AISI 304L	Stainless steel	Stainless steel AISI 304	See Discussion
Hub *Primary Container* *Needle Shield*	Plastic resins	Plastic resins	Plastic resins	See Discussion
Lubricant	Medical grade silicone	Silicon oil	Medical grade silicone	See Discussion

Discussion of differences:

HTL-STREFA S.A. has determined that the Droplet® Pen Needle 34G is substantially equivalent to a predicate device currently cleared for marketing in the United States.

The Droplet® Pen Needle 34G is substantially equivalent to the Terumo® Pen Injector Needle 34 cleared under K140516 in terms of indications for use, compositions, material, design and performance. Specifically, the following performance comparisons were made to determine equivalence to the predicate devices pen needles referenced: length, gauge, biocompatibility, materials, shelf life and sterility. Based on the comparisons above of the predicate devices the Droplet® Pen Needle 34G has raised no different questions of safety and effectiveness.

The intended use of the devices are identical (the injection of fluids subcutaneously), and the indications only differ slightly between the subject device and the predicate. The subject device only differs from Terumo® Pen Injector Needle 34 cleared under K140516 in that insulin is not specified. This difference is adequate because the indications for use is within the scope of the predicate, which specifies for the delivery of drugs.

The difference in needle length between the Droplet® Pen Needle 34G and the predicate device – 3.5 mm (Droplet 34G) vs. 4 mm (Terumo 34G) has also been analyzed. Based on all available design, technical and technological information as well as the published scientific and clinical data, we have concluded that the Droplet 34G, 3.5 mm, with tightened tolerance limits (-0.4mm +0.5mm), is within the same needle length range as the predicate 4mm (±1.25 mm) and thereby substantially equivalent. The results of the bench testing indicate that the Droplet 34G, 3.5mm needle ensures the same level of confidence for needle safety with regard to ensuring subcutaneous injection as the Terumo 34G, 4mm needle.
Finally, available scientific data confirms that a 3.5 mm needles provide reliable subcutaneous drug delivery, as confirmed in clinical study reported by de Berardis et al. in 2018[1].

[1] De Berardis G, Scardapane M, Lucisano G, Abbruzzese S, Bossi AC, Cipponeri E, D'Angelo P, Fontana L, Lancione R, Marelli G, Sciangula L, Nicolucci A. Efficacy, safety and acceptability of the new pen needle 34G × 3.5 mm: a crossover randomized non-inferiority trial; AGO 02 study. Curr Med Res Opin. 2018 Sep;34(9):1699-1704.

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

The difference in sterilization was addressed through validation per ISO 11135-7:2014 and reaching a sterility assurance level(SAL) of 10-6. The ethylene oxide residual levels were found to be 0.0268 mg/device, an acceptable level for the device type and use duration.

The difference in materials of construction were addressed through biocompatibility testing leveraged from the reference device per ISO 10993-1.

HTL-STREFA S.A. has determined that the Droplet® Pen Needle 34G 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 34G 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

Test Parameter	Clause no. & requirement of ISO 11608-2:2012	Result
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 (externally communicating device, blood path indirect) and duration (prolonged contact (>24h to 30 days) were as follows:

1. Cytotoxicity
2. Sensitization
3. Irritation or Intracutaneous Reactivity
4. Acute Systemic Toxicity
5. Subacute/subchronic Toxicity
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 34G did not show any adverse biological / biocompatibility reactions.

Sterility testing:

The DROPLET® PEN NEEDLE 34G is sterilized through Ethylene Oxide. The sterilization methodology has been validated per ISO 11135-7:2014 overkill method (half cycle) with residuals of 0.0267 mg/device at a sterility assurance level (SAL) of 10^{-6}. The device is labeled non-pyrogenic and has been tested through LAL (USP <85>).

- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169-16 and after accelerated aging was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
  - Bubble leak per ASTM 2096

- Shelf life of 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Clinical Performance Data:

[(807.92(b)(2)]

Clinical data is not required.

Conclusion:

[(807.92(b)(3)]

DROPLET® PEN NEEDLE 34G is concluded to be substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate device.