January 7, 2022

Htl Strefa Sa
Justyna Zemigala
RA Manager
ul. Adamówek 7
Ozorków, 95-035
Poland

Re: K211716
Trade/Device Name: DropSafe Safety Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 30, 2021
Received: December 6, 2021

Dear Justyna Zemigala:

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,

CAPT 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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.

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"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

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

[807.92 (a)(1,2)]

Date Summary Prepared:	May 26th, 2021
Submitted By:	HTL-STREFA S.A. ul. Adamówek 7 95-035 Ozorków POLAND Phone: +48 42 270 00 10 Fax: +48 42 270 00 20
Primary Contact:	Justyna Żemigała RA Manager justyna.zemigala@htl-strefa.pl
Secondary Contact:	Izabela Banaś Senior RA Specialist izabela.banas@htl-strefa.pl
Trade Name:	DropSafe Safety Pen Needles
Models:	31G x 5 mm
Common Name:	Insulin 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 devices to which substantial equivalence is claimed is:

Predicate Device:

Manufacturer	Trade Name	510(k) Number
HTL-Strefa S.A.	DropSafe Safety Pen Needle	K170988

Description of Device: [807.92(a)(4)]

Device description

DropSafe Safety Pen Needles are sterile, single-use safety needles intended for use with pen injector devices for the injection of drugs. DropSafe Safety Pen Needles are OTC devices intended to be used by clinical and non-clinical users. DropSafe Safety Pen Needles are already offered in one gage – 31 G and in two lengths: 6mm and 8 mm. This submission covers the addition of a new length: 5 mm with the same gage – 31G. DropSafe Safety Pen Needles are gamma sterilized, non-toxic single use devices.

The device is designed to minimize the risk from accidental needle sticks with a used needle by application of a sharps injury prevention feature. Following use, the needle is locked out preventing reuse. The shield also serves to hide the needle before and after injection.
Each DropSafe safety pen needle is individually packaged in a sealed container. The DropSafe safety pen needle is used by removing the seal and attaching it to the pen injector device to administer a drug subcutaneously. While inserting the needle into the skin at a 90° angle, the slider glides into the shield. While the slider glides into the shield, the safety feature is activated.
Following injection, the slider glides back into its initial position, completely covering the needle where it remains locked. The red safety lock indicator tells the user that the safety lock has been activated. Once the safety pen needle is in the locked mode, it cannot be reused. The safety pen needle is detached from the pen injector device and disposed of into a sharps container.

The pen needle assembly consists of a double-ended cannula that is assembled into an injection molded hub using an adhesive. The hub has internal threads which allows it to be screwed onto the pen injector device. This allows the cartridge end of the needle 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.
An injection molded inner shield is assembled over the patient end of the cannula to prevent needle point damage and accidental needle-sticks. This needle assembly is inserted into a protective injection molded container and sealed with a peel away medical grade paper tab which provides a sterility barrier and tamper evident seal.

Indications for Use: [807.92(a)(5)]

The DropSafe Safety Pen Needles are sterile, single-use safety needles intended for use with pen injector devices for the injection of drugs.

Technological Characteristics: [807.92(a)(6)]

A comparison of characteristics of DropSafe Safety Pen Needles and the predicate device is shown in the table below:

Device Name	**New Device**	**Predicate Device**
Manufacturer	HTL-STREFA S.A.	HTL-STREFA S.A.
510(k) Number	K211716	K170988
Brand name	DropSafe Safety Pen Needle	DropSafe Safety Pen Needle
Intended use	Intended for use with pen injector devices for the injection of drugs	Intended for use with pen injector devices for the injection of drugs
Operation principle	Manual	Manual
Design	Needle assembly – cannula, hub, primary container, seal, needle shield, slider, plug, spring- operated	Needle assembly – cannula, hub, primary container, seal, needle shield, slider, plug, spring-operated
Product Code	FMI	FMI
Length	5 mm	6mm, 8 mm
Gage	31G	31G
Biocompatibility	Conforms to ISO 10993-1 & USP <788> Method 1	Conforms to ISO 10993-1
Sterilization	Gamma radiation	Gamma radiation
Needle tube	Medical Grade Stainless Steel	Medical Grade Stainless Steel
Hub, Primary Container, Shield, Plug	Plastic resin	Plastic resin
Spring	Stainless steel wire	Stainless steel wire

The new 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 indications for use of the new device and the predicate and devices is identical (intended for use with pen injector devices for the injection of drugs).

The only difference between the new device and the predicate device is the needle length on patient end. The new device is 5 mm, whereas the already cleared versions are 6mm and 8mm.

The production process, sterilization process, production facilities and conditions, operation principle, biocompatibility and shelf life aspects are identical for the new and predicate device.

The difference in needle length on patient end between the new device and the predicate device does not raise any new or different questions of safety or effectiveness.

Non-Clinical Performance Data:

[(807.92(b)(1)]

Verification/Validation testing was conducted in compliance with the requirements of ISO 11608- 2:2012 as summarized below. All testing met the applicable requirements.

Parameters and clause from ISO 11608-2:2012	Requirements	Result
4.1 Materials	The needle shall be made of tubing materials specified in ISO 9626	Meets standard
4.2.2 Dimensions	Needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2. Dimensions shall be in accordance with	Meets standard
4.3 Determination of flow rate through the needle	The flow rate is at the border: min 2,14 ml/min	Meets standard
4.4 Bond between hub and needle tube	Clause 9 of ISO 11608-2 and clause 13.1. The union of the hub and needle tube shall not break for at least 5 sec. while a force of at least 11 N is applied	Meets standard
4.5 Needle points	Visually under a magnification of x2,5, needle points shall appear sharp and free from feather edges, burrs and hooks	Meets standard
4.6 Freedom from defects	Visually inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the outer surface of the tubing shall be smooth and free from	Meets standard
4.7 Lubrication	No visible droplets on the outside surface of the	Meets standard
4.8 Dislocation of measuring point at patient end	Clause 8 of ISO 11608-2:2012 maximum allowable dislocation acc. Clause 4.8, Table 2 for 5mm: 0.65m	Meets standard
4.9 Determination of functional compatibility with needle-based	Clause 11 of ISO 11608-2:2012 Needle assembly torque: 0.07 +/- 0.01 Nm Needle hub removal: less than 0.100 Nm Dose accuracy: for doses ≤ 20 ml the calculated values were within ± 0.01 ml of the targeted dose; for doses > 20 ml the calculated values were within ± 5 % of the targeted dose	Meets standard
4.10 Ease of assembly and disassembly		

4.11 Sterility	The needle in its unit packaging has undergone an approved sterilization process. Sterilization method: Gamma irradiation. Sterilization conditions 17,5-40kGy.	Meets standard
6. Pre-conditioning of needles	All pen safety needles to in tested were preconditioned atmosphere in: a dry-heat, a cold-storage, a cyclical atmosphere. Prepared in accordance with the requirements specified in clauses 6.1, 6.2, 6.3 of ISO 11608-2: 2012	Meets standard
12.2.1 Marking on the unit packaging	Any marking on the unit packaging that is essential for the safe use of the NIS shall be visible and easily legible	Meets standard
12.2.2 Marking on the unit packaging	The marking on the unit packaging shall comprise at least the particulars listed in ISO 11608-2:2012 item 12.2.2	
12.2.3 Marking on the user packaging	The marking on the user packaging shall comprise at least the particulars listed in ISO 11608-2:2012 item 12.2.3	

Clinical Performance Data:
[(807.92(b)(2)]

FDA GUIDANCE *Medical Devices with Sharps Injury Prevention Features* (issued on August 9, 2005).

Testing was performed to evaluate the function of the of the safety feature in a simulated clinical environment with the participation of both clinical and non-clinical users. The Simulated Use Study was performed to validate the Instructions For Use (IFU) with the participation of clinical and non-clinical users. As evidenced in the study, the use of this device does not affect the injection technique or the functionality of the pen injector and is safe and effective when used as per the Instructions for Use.

Conclusion:

[(807.92(b)(3)]

DropSafe Safety Pen Needle 5mm is substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate device and does not raise any new questions of safety and effectiveness.