510(k) Summary

K170988

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

[807.92 (a)(1,2)]

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Trade Name:	DropSafe Safety Pen Needles
Models:	31G x 6mm, 31G x 8 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
Becton Dickson & Co.	BD AUTOSHIELD DUO™ PEN NEEDLE	K110703

Secondary Predicate Device

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

The secondary predicate device has been included in this submission to cover the gage and lengths of the New Device – 31G x 6mm and 31G x 8mm. The difference between the New Device and the Secondary Predicate Device is the sharps prevention feature which was added to the New Device. Otherwise, the Secondary Predicate Device and the New Device are identical with regard to raw materials, sterilization method and biocompatibility requirements. The New Device is manufactured in identical production conditions as the secondary predicate device cleared under K143437.

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 offered in one gage – 31 G and in two lengths: 6mm and 8 mm. 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 and the secondary predicate device is shown in the table below:

Device Name	New Device	Predicate Device	Secondary Predicate Device
Manufacturer	HTL-STREFA S.A.	BD AutoShield™ Duo Pen Needle	Droplet Pen Needle
510(k) Number	Pending	K110703	K143437
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	Intended for use with pen injector device for the subcutaneous injection of insulin
Operation principle	Manual	Manual	Manual
Design	Needle assembly – cannula, hub, primary container, seal, needle shield, slider, spring- operated	Needle assembly – cannula, hub, primary container, seal, needle shield, slider, spring- operated	Needle assembly – cannula, hub, primary container, seal, needle shield
Product Code	FMI	FMI	FMI

Device Name	New Device	Predicate Device	Secondary Predicate Device
Length	6mm, 8 mm	5mm	4mm, 5mm, 6mm, 8mm, 10mm, 12mm
Gage	31G	31G	29G, 31G, 32G
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Conforms to ISO 10993-1
Sterilization	Gamma radiation	Gamma radiation	Gamma radiation
Needle tube	Medical Grade Stainless Steel	Medical Grade Stainless Steel	Medical Grade Stainless Steel
Hub, Primary Container and Shield	Plastic resin	Plastic resin	Plastic resin
Spring	Stainless steel wire	Stainless steel wire	n/a
Sharps Prevention feature	Yes	Yes	n/a

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." The indications for use of the new device and the predicate and the secondary predicate devices is identical / substantially equivalent (intended for use with pen injector devices for the injection of drugs / insulin, respectively).

The technological and design differences between the new device and the secondary predicate device do 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.

Test parameter	Requirement – ISO 11608-2:2012	Result
Materials	The needle shall be made of tubing materials specified in ISO 9626.	Meets standard
Dimensions	The needles shall fit the test apparatus specified in clause 7.3 of ISO 11608-2.	Meets standard
Determination of flow rate through the needle	The needle was tested in accordance with Annex A to ISO 11608-2 to determine flow rate through the needle.	Meets standard
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.	Meets standard
Freedom from defects	The needle tube shall fulfill the requirements of ISO 7864, clause 11.3.	Meets standard
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.	Meets standard
Dislocation of measuring point at patient end	Dislocation of the cannula point at the patient end shall be in accordance with Table 2 below when tested in accordance with Clause 8 (of ISO 11608-2).	Meets standard
Determination of functional compatibility with needle-based injection systems	Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11.	Meets standard
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.	Meets standard
Pre-conditioning of needles	All requirements of the standard related to preconditioning of needles were met.	Meets standard

DropSafe Safety Pen Needle & pen injector compatibility – pen injectors available and cleared in the USA:

Manufactured by	Brand:
Eli Lilly	**HumaPen® L U X U R A HD** **HumaPen® L U X U R A** **HumaPen® savvio** **HumaPen® E r g o** **HumaPen® E r g o II**
Owen Mumford	**Autopen®**
Haselmeier	**TactiPen®**
Novo Nordisk	**NovoPen®**

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 Needles are substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate device and the secondary predicate and do not raise any new questions of safety and effectiveness.