December 2, 2022

Pikdare SpA
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K223353
Trade/Device Name: DropSafe™ Sicura™
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 30, 2022
Received: November 2, 2022

Dear Dave Yungvirt:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2022.12.02 11:41:35 -05'00'

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

510(k) Number *(if known)*
K223353

Device Name
DropSafe™ Sicura™

Indications for Use *(Describe)*
The DropSafe™ Sicura™ are sterile, single-use passive safety injection needles to be used in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection

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 - K223353

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: July 20, 2022

Submitted By:

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Trade Name: DropSafe™ Sicura™

Models:

Reference number	Description
02094000180250	**DropSafe™ Sicura™** G18X25
02094000210250	**DropSafe™ Sicura™** G21X25
02094000220250	**DropSafe™ Sicura™** G22X25
02094000230250	**DropSafe™ Sicura™** G23X25
02094000250160	**DropSafe™ Sicura™** G25X16
02094000250250	**DropSafe™ Sicura™** G25X25
02094000270130	**DropSafe™ Sicura™** G27X13
02094000300130	**DropSafe™ Sicura™** G30X13

Common Name: Passive Safety Injection 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 are:

Manufacturer	Trade Name	510(k) Number
Terumo Europe NV	K-pack SurshieldTM	K111797

Description of Device:

[807.92(a)(4)]

Device description

DropSafe^{TM} Sicura^{TM} are Sterile, single-use passive safety injection needles to be used in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection.
DropSafe^{TM} Sicura^{TM} are single patient and used by HCP (Healthcare professionals: nurses, pharmacist and physician).
DropSafe^{TM} Sicura^{TM} passive safety injection needles, are hypodermic needles intended for subcutaneous and intramuscular injection of fluids using syringes with male luer slip or luer lock fitting. Passive safety injection needles are equipped with passive sharps prevention feature. They are sterilized with ETO. Non-toxic single use, single patient devices.
The device is designed to minimize the risk from accidental needle sticks with an already used needle by application of a sharps injury prevention feature. Following use, the slider of the needle is automatically locked out preventing reuse. The needle is protected by an external cover, the cover must be in place during the connection between the needle and the syringe.
After removing the external cover the needle is still protected by a transparent slider, the slider will protect the needle and the user during the injection activity (sharp prevention feature). The slider is transparent for allowing the user to have a clear view of the cannula during the injection.
During the injection the slider progressively uncovers the cannula; this action is possible thanks to the presence of two components (spring and sleeve) which let the slider moves up and down.
Once the injection is done and the needle removed from the skin, the slider automatically covers the cannula and remain blocked, guaranteeing the sharp prevention feature.
The confirmation about the blocking is done thanks to the appearing of red marks visible through the housing.
DropSafe^{TM} Sicura^{TM} is not intended to be used for the drawing up of drugs from vials and/or ampule, for which it's indicated to use blunt needles.

Each **DropSafe^{TM} Sicura^{TM}** is individually packaged in a sealed container. The **DropSafe^{TM} Sicura^{TM}** is used by opening the blister and applying the needle on a syringe filled with drug. While inserting the needle into the skin at a 90° or 45° angle (with or without skin fold), the

slider glides into the housing. While the slider glides into the housing, 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 **DropSafe™ Sicura™** is in the locked mode, it cannot be reused. The **DropSafe™ Sicura™** is detached from the syringe and disposed of into a sharps container according to local requirements.

The **DropSafe™ Sicura™** assembly consists of a cannula that is assembled into an injection molded hub using an UV glue. The hub has been designed in order to guarantee a proper connection with luer lock and luer slip nozzle of syringes. The cannula is lubricated using a silicone-based lubricant for ease of injection and thus reduce friction during the injection. The other components that are assembled onto hub/cannula components are stain less steel spring, injection molded housing, sleeve with red coloured stripes and slider. The coupling of spring, sleeve and slider let have the safety prevention feature of the device, avoiding accidental needle-sticks. This needle assembly is inserted into a protective injection molded cover and blistered with a peel away medical grade paper which provides a sterility barrier.

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Indications for Use:

[807.92(a)(5)]

The **DropSafe™ Sicura™** are sterile, single-use passive safety injection needles to be used in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection.

Technological Characteristics:

[807.92(a)(6)]

A comparison of characteristics of **DropSafe™ Sicura™** and the predicate devices is shown in the table below:

Device Name	**New Device**	**Predicate Device**
Manufacturer	Pikdare SPA	Terumo Europe NV
510(k) Number	K223353	K111797
Intended use	Sterile, single-use passive safety injection needle to be used in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection	A single use injection needle with an integrated passive sharps protection feature designed to reduce needle stick injury and to be used in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection
Indication for use	Sterile, single-use passive safety injection needle to be used in combination with a (pre-)filled syringe for subcutaneous and intramuscular injection	The K-Pack Surshield™ Needle is a sterile hypodermic needle for single use with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with hypodermic syringes for subcutaneous and intramuscular injection.
Operation principle	Manual	Manual

Design	Injection moulded Hub Cannula Glue Spring Injection moulded Sleeve Injection moulded Slider Injection moulded Housing Injection moulded Cover Blister	Injection moulded hub Cannula Glue Injection moulded tube Spring Injection moulded grip Injection moulded sleeve Injection moulded slider Injection moulded housing Injection moudled case Injection moulded cap Paper seal
Product Code	FMI	FMI

Device Name		Subject Device	Predicate Device
Length		25 mm - 16 mm - 13mm	1/2" (12mm)
Gauges		G18 - G21 - G22 - G23 - G25 - G27 - G30	27G
Materials	*Cannula*	Stainless Steel	StainlessSteel
	Hub	Polypropylene Medical Grade	Polypropylene
	Housing	Polypropylene Medical Grade	Plastic moulded part
	Cover	Polypropylene Medical Grade	Plastic moulded part
	Slider	Polycarbonate Medical Grade (PC)	Plastic moulded part
	Sleeve	ABS (Food grade)	Plastic moulded part
	Spring	Stainless steel wire	Stainless steel wire
	Glue	UV Glue	UV Glue
	Lubricant	Silicone Medial Grade	Silicone Medical Grade
	Blister	Medical Paper and Plastic Film	
Biocompatibility		Conforms toISO 10993-1	Conforms to ISO 10993-1
Sterilization		Ethylene Oxide	Ethylene Oxide

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 intended use of the devices is identical (intended for use with pre-filled syringes). Based upon the above comparisons to the predicate device, DropSafe™ Sicura™ passive safety injection needles do not raise any new issues of safety of effectiveness

Reference Device

Manufacturer Name	Trade Name	510(k) Number
Terumo Corp	SurGuard 2 Safety Needle	K051865

The reference device has been included in this submission to cover the gage and lengths of the New Device. The difference between the New Device and the Reference Device is the sharps prevention feature: the new device includes a sharp prevention feature based on an active sharp prevention system and Reference Device includes a Sharp prevention feature based on a passive sharp prevention system. The Reference device has been considered taking into account the offered lengths and gauges of the hypodermic needle included in a safety needle.

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Non-Clinical Performance Data:

[(807.92(b)(1)]

Verification/Validation testing was conducted in compliance with the requirements of ISO 7864:2016, ISO 9626:2016, ISO 23908:2011 and ISO 80369-7:2021 as summarized below. All testing met the applicable requirements.

Test parameter	Requirement	Result
Cannula Materials	The needle shall be made of tubing materials specified in ISO 9626:2016 and ISO 15510:2014.	Meets standard
Dimensions	The needles diameters are in compliance with clause 4.10.1 of ISO 7864:2016 and requirements of ISO 9626:2016. Tolerances on lengths shall be in accordance to ISO 7864:2016(clause 4.10.2)	Meets standard
Bond between hub and needle tube	The union of the hub and needle tube shall not break when tested in accordance to ISO 7864 (Clause 4.12).	Meets standard
Freedom from defects	The needle tube shall fulfill the requirements of ISO 7864 (clause 4.10.3)	Meets standard
Lubrication	The needle tube should be lubricated. The lubricant shall not, under normal or corrected- to-normal vision, bevisible as droplets of fluid on the outer or inner surfaces of the needle tube. The quantity of lubricant used should not exceed 0,25 mg/cm^2 of the lubricated surface area of the needle tube	Meets standard
Cleanliness	When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter. When examined under 2,5× magnification, the hub socket (fluid path surface) shall appear free from particles and extraneous matter.	Meets standard
Limits for Acidity or Alkalinity	When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex A shall be within one unit of pH of that of the control fluid.	Meets standard

Limits for extractable metals	When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with Annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0,1 mg/l	Meets standard
Color of hub	The hub shall be made either of pigmented or of unpigmented material. If pigmented, the color shall be in accordance with ISO 6009.	Meets standard
Needle point	When examined under 2,5× magnification the needle point shall appear sharp and free from feather edges, burrs and hooks. The needle point should be designed so as to minimize coring and fragmentation when penetrating vial closures Penetration testing can provide an indication of the needle point sharpness and lubrication	Meets standard
Patency of lumen	the flow rate of water through the needle shall not be less than 80 % of an unprocessed needle tube of equivalent outer diameter and length having a minimum inner diameter in accordance with ISO 9626 when tested under the same pressure.	Meets standard
Sharp injury protection	The needle shall meet the requirements of ISO 23908, the conformity to this standard has been verified also through usability and Sharps injury prevention studies	Meets standard
Hub conical fitting	The conical socket of the hypodermic needle hub shall meet the requirements of ISO 80369-7	Meets standard
Sterility and Biocompatibility	The needle in its unit packaging shall have been subjected to a validated sterilization process resulting in a Sterility Assurance Level of at least 10−6 in accordance with recognized ISO standards. The needle shall be free from biological hazard in accordance with the requirements of ISO 10993-1.	Meets standard

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

Conclusion:

[(807.92(b)(3)]

DropSafe™ Sicura™ is substantially equivalent in the intended use, technology/principle of operation and performance to the predicate devices and do not raise any new questions of safety and effectiveness.