



June 26, 2023

Owen Mumford Ltd
Darren Mansell
Regulatory Affairs Manager
Brook Hill
Woodstock, Oxfordshire OX20 1TU
United Kingdom

Re: K231124

Trade/Device Name: Unistik® 3 Single-Use Safety Lancets:- Extra (21G), Normal (23G), Comfort (28G), Gentle (30G)

Regulation Number: 21 CFR 878.4850

Regulation Name: Blood Lancets

Regulatory Class: Class II

Product Code: FMK

Dated: April 18, 2023

Received: April 20, 2023

Dear Darren Mansell:

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,

Mark Trumbore -S Digitally signed by
Mark Trumbore -S
Date: 2023.06.26
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Mark Trumbore, Ph.D.
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Enclosure

SECTION 4.0

INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known)
K231124

Device Name
Unistik® 3

Indications for Use (Describe)

The Unistik® 3 single-use safety lancets are hand-held, disposable devices intended to be used to achieve a controlled skin puncture, typically on the fingertip, to obtain a capillary blood specimen.

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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SECTION 5.0
510(k) SUMMARY

SECTION 5.0

510(k) SUMMARY

1. Submitter

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Date Prepared: 18 April 2023

2. Device

Name of Device: Unistik® 3 Single-Use Safety Lancets

Common Name: Blood lancets

Classification Name: Single use only blood lancet with an integral sharps injury prevention feature

Regulatory Class: II

Product Code: FMK

3. Predicate Devices

Predicate Device Name: Unistik® 3 Single-Use Safety Lancets
under 510k number K221126

(Cleared for: Prescription Use and Over-The-Counter Use)

4. Description of The Device

This submission covers the following devices:

- Unistik® 3 Single-Use Safety Lancets 21G, 23G, 28G & 30G (new design variants)

The Unistik® 3 sterile single-use safety lancets are hand-held disposable devices intended to be used to achieve a controlled skin puncture, typically on the fingertip, in order to obtain a capillary blood specimen. The Unistik® 3 sterile single-use safety lancets are indicated for use where a capillary blood specimen is required for the purposes of performing in-vitro diagnostic (IVD) assays, e.g. for blood glucose monitoring in patients with diabetes.

The Unistik® 3 new design variant safety lancets are available in four different gauges; 21G, 23G, 28G and 30G, to facilitate appropriate blood flow rates from the skin puncture.

The Unistik® new design variant safety lancets are designed for prescription and over-the-counter use and to be used by self-testing patients, care-givers and healthcare professionals. The devices are designed to perform a controlled skin puncture on the fingertip, in order for care-givers and healthcare professionals to obtain capillary blood specimens from patients for IVD assays, and also for lay (home) users to be able to perform a skin puncture on themselves where an IVD self-testing regime is required. The intended user population includes male and female, right or left-handed self-administering patients, care givers and healthcare professionals. The frequency of use and intended patient population is dependent on the given diagnostic regime.

The Unistik® 3 new design variant safety lancets are sterile single-use devices with integral sharps protection whereby the lancet needle is shielded before and after use to prevent needlestick injuries, thereby mitigating the hazard of transmission of blood-borne infectious agents. Furthermore, the device automatically self-disables after a single use, thus preventing any hazards of re-use.

The Unistik® 3 new design variant safety lancets are used by first twisting off the end cap, the needle tip is then exposed but remains safely shielded within the device housing. The user then presses the end face of the device against the sampling site, then activates the device by pressing the release button on the side of the device. The lancet needle is then automatically propelled forward by the internal pre-loaded spring to lance the skin and also automatically retracted by the spring back inside the device housing, where it is then automatically locked to prevent re-use. After firing, the locked position of the needle tip inside the device ensures that it remains safely shielded, and the device can be safely disposed of into an appropriate sharps receptacle.









The Unistik® 3 new design variant safety lancets consist of a stainless steel lancet needle moulded into a plastic lancet holder component, which in turn is assembled into a moulded plastic outer housing with a pre-loaded steel firing spring for propelling the lancet holder forward when the device is activated and a retraction spring for subsequently automatically retracting it. After retraction, the lancet holder is automatically locked into the device such that the device cannot be re-used and the needle tip is safely shielded such that it is inaccessible within the body of the device.

The lancet needles are moulded into the lancet holder component such that the needle tip is sealed by complete encapsulation in overmoulded plastic. The complete lancet holder component is then sterilised by gamma irradiation, so after irradiation the sterility of the needle tip is maintained by encapsulation within the plastic. The sterile seal is only broken when the user twists off and removes the lancet cap immediately before use. The needle tip is the exposed needle length after the cap is removed, and this is the only part of the needle that will penetrate the patient's skin during use. Therefore, the encapsulation of the needle tip by plastic overmoulding performs the function of primary packaging, whereby a sterile seal is maintained until the point of use.

The purpose of this 510(k) application is to obtain both prescription-only clearance and over-the-counter clearance for the Unistik® 3 new design variant safety lancets. The intended use for the Unistik® 3 new design variant safety lancets remains the same as the predicate device.

Table 5.1 on the following page illustrates the Unistik® 3 21G, 23G, 28G & 30G new design variants in comparison to the existing Unistik® 3 21G, 23G, 28G & 30G variants cleared under .K221126.

Table 5.1 - Illustrations of Unistik® 3 21G, 23G, 28G & 30G new design variants in comparison to the existing Unistik® 3 variants (not to scale)

Unistik®3 safety lancet range – predicate design cleared under K221126	Unistik®3 safety lancet range – new design variants in this submission
<p>30G Device - Predicate</p>  <p>A white plastic safety lancet with a purple translucent tip and a white sliding cover.</p>	<p>30G Device – New design variant</p>  <p>A white plastic safety lancet with a red translucent tip and a white sliding cover.</p>
<p>28G Device – Predicate</p>  <p>A purple plastic safety lancet with a white translucent tip and a white sliding cover.</p>	<p>28G Device – New design variant</p>  <p>A white plastic safety lancet with a purple translucent tip and a white sliding cover.</p>
<p>23G Device – Predicate</p>  <p>A yellow plastic safety lancet with a blue translucent tip and a white sliding cover.</p>	<p>23G Device – New design variant</p>  <p>A white plastic safety lancet with a yellow translucent tip and a white sliding cover.</p>
<p>21G Device – Predicate</p>  <p>An orange plastic safety lancet with a dark blue translucent tip and a white sliding cover.</p>	<p>21G Device – New design variant</p>  <p>A white plastic safety lancet with an orange translucent tip and a white sliding cover.</p>

5. Indications for Use

The Unistik® 3 new design variant single-use safety lancets are hand-held disposable devices intended to be used to achieve a controlled skin puncture, typically on the fingertip, to obtain a capillary blood specimen.

6. Technological Characteristics

The Unistik® 3 new design variant safety lancets are substantially equivalent to the predicate device, the Unistik® 3 safety lancet.

A comparison of the intended uses and technological characteristics of the Unistik® 3 new design variant safety lancets to the predicate Unistik® 3 devices is summarised in Table 5.2 below.

Table 5.2 - Characteristics of the Unistik® 3 new design variant safety lancets (submission device) in comparison to the predicate device

Device Characteristic	Predicate Device: Unistik® 3 Safety Lancets - K221126	Submission Device - Unistik® 3 Safety Lancets – 21G, 23G, 28G & 30G (new design variants)
Indications For Use	The Unistik® 3 safety lancets are hand-held, disposable devices intended to be used to achieve a controlled skin puncture, typically on the fingertip, to obtain a capillary blood specimen.	Unchanged from the predicate device.
Use environment	Home and clinical.	Unchanged from the predicate device.
Operating principle	Manually activated (side fire button) spring-powered automatic lancing and needle retraction.	Unchanged from the predicate device.
Design/ construction	Stainless steel lancet needle moulded into a plastic lancet holder component, which in turn is assembled into a moulded plastic outer housing with a pre-loaded steel lancet firing spring. The external plastic outer housing incorporates a plastic tab which functions as the firing button on the side of the device.	Unchanged from the predicate device with the exception of an additional spring for lancet retraction and a trigger component which internally engages with the lancet holder and externally functions as the firing button.

Table 5.2 (continued) - Characteristics of the Unistik® 3 new design variant safety lancets (submission device) in comparison to the predicate device

Device Characteristic	Predicate Device: Unistik® 3 Safety Lancets - K221126	Submission Device - Unistik® 3 Safety Lancets – 21G, 23G, 28G & 30G (new design variants)
Integral sharps injury prevention feature?	Yes	Unchanged from the predicate device
Single-use?	Yes	Unchanged from the predicate device
Sterility	Sterile	Unchanged from the predicate device
Components and Materials	Plastic external and internal components, stainless steel needle and steel spring.	Unchanged from the predicate device, though some changes in precise material specifications of the plastics and steels.
Package	Laminate pulp board cartons	Unchanged from the predicate device.

Table 5.2 (continued) - Characteristics of the Unistik® 3 new design variant safety lancets (submission device) in comparison to the predicate device

Device Characteristic		Predicate Device: Unistik® 3 Safety Lancets - K221126	Submission Device - Unistik® 3 Safety Lancets – 21G, 23G, 28G & 30G (new design variants)
Needle Specifications	Needle Gauges (SWG)	Unistik® 3 existing design: 18G, 21G, 23G, 28G, 30G	Unistik® 3 new design variants: 21G, 23G, 28G, 30G The Unistik® 3 new design variant gauge range of 21G to 30G is within the range of Unistik® 3 existing design gauges (18G – 30G)
	Lancing Depths (mm)	Unistik® 3 existing design: 18G variant: 1.8 mm depth ± 0.35 mm 21G variant: 2.0 mm depth ± 0.35 mm 23G variant – 1.8 mm depth ± 0.35 mm 28G variant – 1.8 mm depth ± 0.35 mm 30G variant – 1.5 mm depth ± 0.35 mm	Unistik® 3 new design variants: 21G new variant: 2.0 mm depth (Min. 1.49 mm / Max. 3.01mm) 23G new variant: 1.8 mm depth (Min. 1.29 mm / Max. 3.01 mm) 28G variant: 1.8 mm depth (Min. 1.29 mm / Max. 3.01 mm) 30G variant: 1.5 mm depth (Min. 0.99 mm / Max. 3.01 mm) The range of nominal lancing depths for the Unistik® 3 new design variants (1.5 mm to 2.0 mm depth) is the same as the depth range offered by the existing Unistik® 3 design.
	Needle Tip Configuration	2-facet chisel (18G) 3-facet (21G) 3-facet -(23G) 3-facet (28G) 3-facet (30G)	3-facet (21G) 3-facet -(23G) 3-facet (28G) 3-facet (30G) The Unistik® 3 new design variants have the same 3-facet needle tips as the corresponding gauges of the existing Unistik® 3 design.
	Sterilisation method	20-40 kGy Cobalt 60 gamma radiation validated to achieve 10 ⁻⁶ sterility assurance level (SAL).	25-50 kGy Cobalt 60 gamma radiation validated to achieve 10 ⁻⁶ sterility assurance level (SAL)

7. Performance Data

Non-clinical performance data – bench testing:

Design verification testing of the Unistik® 3 new design variant safety lancets has been carried out to evaluate the performance of the devices against defined acceptance criteria. Table 5.3 below provides a summary of the relevant design verification testing.

Table 5.3 – Design verification tests carried out on Unistik® 3 new design variants

Test Description	Result
Visual inspection and numbering	Pass
Standard pre-conditioning	Pass
Premature activation	Pass
Torque to rotate cap	Pass
Force to actuate	Pass
Needle retention force	Pass
Needle safety test	Pass
Depth of Penetration	Pass
Needle safety after drop testing	Pass
Simulated clinical use testing	Pass

The design verification testing has established that the Unistik® 3 new design variant safety lancets comply with the acceptance criteria established based on the specifications of the devices. The results from these tests demonstrate that the Unistik® 3 new design variant safety lancets are safe and effective when used as intended.

Simulated clinical use testing:

Simulated clinical use testing has been carried for the Unistik® 3 new design variant safety lancets according to the relevant FDA Guidance – (Medical Devices with Sharps Injury Prevention Features, August 9, 2005). The Unistik® 3 new design variant safety lancets achieved the performance criteria specified for the simulated clinical use testing.

Human factors analysis:

Human factors analysis has been carried out for the Unistik® 3 new design variant safety lancets which concluded that they are safe and effective for their intended users.

Biocompatibility:

Biocompatibility evaluations have been carried out for the Unistik® 3 new design variant safety lancets and have established the compliance of the devices to ISO 10993-1 requirements.

Sterilisation:

The sterility of the devices is assured using a sterilisation method validated in accordance with ISO 11137-1- "Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices".

Through the sterilisation methods used, all devices are sterilised to provide a Sterility Assurance Level (SAL) of 10^{-6} .

8. Conclusion

In summary, the differences between the Unistik® 3 new design variant safety lancets and the predicate device have no impact on safety and effectiveness and the products are therefore substantially equivalent to the predicate device.