August 12, 2022

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

Re: K221126
Trade/Device Name: Unistik® 3, sterile single-use safety lancets; Unistik® 3 Value, sterile single-use safety lancets; Abbott SF sterile single-use safety lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 8, 2022
Received: July 12, 2022

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,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221126

Device Name
Unistik® 3, sterile single-use safety lancets
Unistik® 3 Value, sterile single-use safety lancets
Abbott SF sterile single-use safety lancets

Indications for Use *(Describe)*
The 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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510(k) SUMMARY

1. Submitter

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Date Prepared: 08 July 2022

2. Device

Name of Device: Unistik® 3, sterile single-use safety lancets,

Unistik® 3 Value, sterile single-use safety lancets,

Abbott SF sterile 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: SurgiLance® Safety Lancet, under 510k number K101145.

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

4. Description of The Device

This submission covers the following devices:

- Unistik® 3, sterile single-use safety lancets
- Unistik® 3 Value, sterile single-use safety lancets
- Abbott SF® sterile single-use safety lancets

The Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets are hand-held disposable devices intended to be used to achieve a controlled skin puncture on the fingertip, in order to obtain a capillary blood specimen. The Unistik® 3 sterile single-use safety lancets and Abbott SF 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 safety lancets are available in five different variants, each with a different needle gauge (18G, 21G, 23G, 28G, 30G) to facilitate appropriate blood flow rates from the skin puncture. There are two high flow variants (18G, 21G) one medium flow variant (23G) and two low flow variants (28G, 30G). The Unistik® 3 Value devices are identical to the equivalent gauge of Unistik® 3 devices, except for the colour of the plastic body housings. The Unistik® 3 Value devices all have a vanilla body housing colour, whereas the Unistik® 3 devices have a different colour for each gauge.

In the remainder of this submission, the Unistik® 3 safety lancets and Unistik® 3 Value safety lancets will both be referred to as “the Unistik® 3 safety lancets.”

The Abbott SF sterile single-use safety lancets are available in a single configuration only (28G needle).

The Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use 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 sterile single-use safety lancets and Abbott SF sterile single-use 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, so 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 sterile single-use safety lancets and Abbott SF sterile single-use 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 sterile single-use safety lancets and Abbott SF sterile single-use 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 spring for propelling the lancet holder forward when the device is activated and 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.

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-counter clearance for the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets. The intended use for the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets remains the same as the predicate device.

5. Indications for Use

The 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 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets are substantially equivalent to the predicate device, the SurgiLance® Safety Lancet.

A comparison of the intended uses and technological characteristics of the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets to the predicate SurgiLance® devices is summarised in the table below.

Device Characteristic	**Predicate Device: SurgiLance® Safety Lancets – K101145.**	**Submission Device - Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets**
Indications For Use	The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury.	Equivalent to the predicate device
Use environment	Home and clinical	Home and clinical
Operating principle	Contact-activated spring-powered automatic lancing and needle retraction.	Manually activated (side fire button) spring-powered automatic lancing and needle retraction.
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 spring	Unchanged from the predicate device with the exception of an addition of a plastic tab functioning as a firing button which is incorporated into the external plastic outer housing.
Integral sharps injury prevention feature?	Yes	Unchanged from the predicate device

Device Characteristic		Predicate Device: SurgiLance® Safety Lancets – K101145.	Submission Device - Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets
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, but likely that plastic and steel specifications used differ from predicate.
Package		Laminate pulp board cartons	Unchanged from the predicate device.
Needle Specifications	Needle Gauges (SWG)	18G, 21G	Unistik 3: 18G, 21G, 23G, 28G, 30G Abbott SF: 28G The predicate device is available in 18G and 21G variants only, therefore the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets represent an extended range of higher gauges (smaller needle diameters) compared to the predicate.

Device Characteristic		Predicate Device: SurgiLance® Safety Lancets – K101145.	Submission Device - Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets
	Lancing Depths (mm)	1.8 mm & 2.3 mm (18G) 1.0 mm, 1.8 mm, 2.2 mm & 2.8 mm (21G)	Unistik 3: 1.4mm, 1.5mm. 1.8mm, 2.0mm Abbott SF: 1.4mm The Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets lancing depth range falls within the range offered by the predicate device, i.e. 1.4 mm - 2.0 mm compared to the predicate range of 1.0 mm - 2.8 mm.
	Needle Tip Configuration	Not known.	2-facet chisel - 1.8 mm (18G) 3-facet - 2.0 mm (21G) 3-facet - 1.8 mm (23G) 3-facet - 1.8 mm (28G) 3-facet - 1.5 mm (30G)
	Sterilisation method	Not known.	20-40 kGy Cobalt 60 gamma radiation validated to achieve a sterility assurance level (SAL) of 10^{-6}.

Table 6.1: Comparison of Characteristics between Submission Devices and Predicate Device

7. Performance Data

Non-clinical performance data:

Design verification testing of the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets has been carried out to evaluate the performance of the devices against defined acceptance criteria.

The following table provides a summary of the relevant design verification testing.

Bench Testing:

Table 7.1: Summary of the performance tests

Test	Requirement	Results
Integrity of device	Internal test specification	Meets specification
Test firing protocol	Internal test specification	Meets specification
Environmental testing	Internal test specification	Meets specification
Cap removal torque and needle retention	Internal test specification	Meets specification
Needle penetration measurement	Internal test specification	Meets specification
Drop test	Internal test specification	Meets specification

Additionally, performance testing other than the above was conducted on the devices. The devices comply with the acceptance criteria established based on the specifications of the devices. All additional performance tests met the acceptance criteria.

The results from these tests demonstrate that the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets are safe and effective when used as intended.

Biocompatibility:

Biocompatibility evidence per ISO 10993-1 is available for some of the materials of the Unistik® 3 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets.

Sterilisation:

The sterility of the devices is assured using a sterilisation method validated in accordance with ISO 11137 “Medical Devices – Validation and Routine Control of Radiation Sterilisation”. 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 sterile single-use safety lancets and Abbott SF sterile single-use safety lancets and the predicate device have no impact on safety and effectiveness and the products are therefore substantially equivalent to the predicate device.