10/24/2022

NSP Tech Pte Ltd
Hc Tan
Operations Manager
10 Admiralty Street, Northlink Building, #02-06
Singapore, 757695
Singapore

Re: K221783
Trade/Device Name: SafetiCET (SC-150);SafetiCET (SC-180);SafetiCET (SC-220);SafetiCET (SC-250);SafetiCET (SC-250B)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 29, 2022
Received: September 1, 2022

Dear Hc Tan:

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,

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)*
K221783

Device Name
SafetiCET Safety Lancet

Indications for Use *(Describe)*
The device is designed for obtaining capillary blood sample.

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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K221783

510(k) Summary
SafetiCET Blood Lancet

1. SUBMITTER:

Applicant Name:

NSP Tech Pte Ltd
10 Admiralty Street,
Northlink Building, #02-06
Singapore 757695

Contact Person:

Name : HC Tan
Phone : (65)98180450
Fax : (65)67476533
Email : hockchoon.tan@nsptech.com.sg

Establishment registration number 3008337059

Date prepared : 21st October 2022

2. DEVICE

Trade Name	:	SafetiCET Safety Lancet
Common Name	:	Blood Lancet
Regulatory Class	:	Class II (special controls)
Classification Name	:	Single Use Only Blood Lancet with an Integral Sharps Injury Prevention Feature
Product Code	:	FMK
Regulation Number	:	21 CFR § 878.4850 (special controls)
Review Panel	:	General & Plastic Surgery
Device 510K number	:	K221783

3. PREDICATE DEVICE

VeriFine Safety Lancet
Regulatory Class II
Product Code FMK
General & Plastic Surgery
Predicate device 510K number: **K221368**

4. DEVICE DESCRIPTION:

The SafetiCET Safety Lancet is single use only blood lancet used to puncture the skin to obtain a drop of blood for diagnostic purposes. It is a disposable blood lancet intended for a single use and the device is comprised of a needle encased in a housing made with plastic material commonly used for medical devices. The mechanism of the device includes an integral sharps injury prevention feature which allows the device to be used only once and then renders it inoperable and incapable of further use.

510(k) Summary
SafetiCET Blood Lancet

The SafetiCET Safety Lancet is a sterile device and the sterilization is done using the Gamma Irradiation means.

5. INTENDED USE

The device is used for obtaining capillary blood sample.

6. INDICATION FOR USE STATEMENT

The device is designed for obtaining capillary blood sample.

7. SUBSTANTIAL EQUIVALENCE COMPARISON

TABLE OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

	SafetiCET Safety Lancet	**VeriFine Safety Lancet**
510 (k) Number	K221783	K 221368
Classification	Class II	Class II
Product Code	FMK	FMK
Intended Use	The device is designed for obtaining capillary blood sample.	It is intended for capillary blood sampling.
Indication For Use	The device is designed for obtaining capillary blood samples.	It is intended for capillary blood sampling.
Manufacturer	NSP Tech Pte Ltd	Promisemed Hangzhou Meditech Co., Ltd.
Sterilizer	Grandten	Not known
Needle Gauge	21G, 23G, and 28G	18G, 21G, 23G, 25G, 26G, 28G, 30G

510(k) Summary
SafetiCET Blood Lancet

	SafetiCET Safety Lancet	VeriFine Safety Lancet
Sterilization	Gamma Radiation sterilization	Gamma Radiation sterilization
Sterility	Meet the Sterility Assurance Level of 10^{-6} as per the requirement of ISO 11137-1:2006	Not known
Use	Single-Use only	Single-Use only
Bio compatibility	ISO 10993 series	ISO 10993 series
Shelf Life	5 years	Not mentioned

8. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The SafetiCET Safety Lancet has similarities with the predicate device in areas such as Intended Use, Indications For Use, Sterilization means.

The results of measuring penetration depth of the subject device are in the same range of the needle length of the predicate device. There is no significant difference in technological characteristics between the subject device and the predicate device.

Performance tests and comparison tests on the device quality confirmed the safety and effectiveness of the device.

In summary, the subject device and predicate device are said to have same technological characteristics.

510(k) Summary
SafetiCET Blood Lancet

9. PRODUCT SAFETY AND EFFECTIVENESS DATA

Product Safety Design and Effectiveness	The housing of the device encases the Needle and device has a protective cap attached to the housing. This combination prevents any needle stick issue with user or patient before the device is activated. The safety relating to needle stick issue is further enhanced with the needle encapsulated by a plastic molded over it when residing in the housing of the device. This encapsulation is only removed when the protective cap is detached from the housing with a force known as the Twist Break Force preparing the device for activation and use. The encapsulation of the needle also allows it to remain sterile after the device has undergone sterilization process. This prevents any inadvertent pathogen contamination or contact to user or patient before use. The device is activated by pushing the device on the blood collection area of the patient. Once activated, the needle is pushed out of the housing by the Trigger Spring. After the device has performed the piercing or penetration operation, the Return Spring pushes the needle back into the housing preventing any needlestick issue. The Trigger Spring helps in attaining the effectiveness of the device in providing the penetration operation essential for the blood sample collection. The Return Spring helps in accomplishing the safety of the device by ensuring that the needle retracts into the housing after the penetration operation is completed.
Test Principle	Both the subject device and the predicate device adopt the same test operation principle of capillary blood sample collection. The device is first placed on the blood collection area of the patient and using contact activation means, the automatic mechanism is activated with the needle coming out of the device housing to make the piercing or penetration operation. After the penetration operation is completed, the needle automatically retracts into the housing. Because of the construction of the mechanism, the needle cannot be pushed out of the housing for a second round of penetration preventing the device from being reused. After use, the device is to be discarded in a suitable biohazard container. The blood collection operation is controlled for its depth of the penetration. This is done by the design of the parts operating in the device. Hence, the device is checked for Penetration Depth as part of its performance assessment. The protective cap is able to break the encapsulation of the needle when the twisting force is applied on the cap. This twisting force also allows the cap to be detached from the housing preparing the device for the penetration operation. Here, the Twist Break Force is measured as part of device performance assessment.

510(k) Summary
SafetiCET Blood Lancet

10. PERFORMANCE TESTING SUMMARY

The following performance testing done on the subject device is compared against that of the predicate device.

- Sterilization testing and Validation
- Penetration depth test
- Twist break force test
- Drop test
- Joint strength of needle-to-needle holder test
- Joint strength of top cover to housing test
- Puncture resistance test
- Needle retraction test
- Mechanical properties test of material

11. CONCLUSION

The comparison and evaluation of the device features, intended use, indication for use statement, and performance tests demonstrate substantial equivalence between the subject device and the predicate device. For the Safety and Effectiveness test, the subject device provides same safety and effective performance as the predicate device. From the evaluation above, we can deem that the SafetiCET Safety Lancet is substantially equivalent to the predicate device.