August 22, 2022

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

Re: K221604
Trade/Device Name: SafetiHeel, MediHeel, Novaplus
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 2, 2022
Received: August 5, 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,

Colin Chen
Acting 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)*
K221604

Device Name
SafetiHEEL Safety Lancet, MediHEEL Safety Heelstick, Novaplus Safety Heelstick

Indications for Use *(Describe)*
The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.

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
SafetiHeel Safety 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 : March 20, 2022

2. DEVICE

Trade Name	:	SafetiHeel, MediHeel, Novaplus
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

3. PREDICATE DEVICE

The predicate device used for the study shall be the predecessor device which is also the preamendments device of the SafetiHeel Safety Lancet. The latter is currently registered under Class I with listing FDA device listing number, D117836.

Regulatory Class: Class I

Product Code: FMK

Review Panel: General & Plastic Surgery

FDA Device Listing Number: D117836

510(k) Summary
SafetiHeel Safety Lancet

4. DEVICE DESCRIPTION:

The SafetiHeel 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 blade 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.

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

The SafetiHeel device is marketed under model numbers SH-065, SH-085, SH-100 and SH-150. The device is also marketed under trade names such as MediHeel and Novaplus in the USA market. The models for the MediHeel include model number 1003, 1004, 1005 and 1006. For the Novaplus device, the model numbers are 10041 and 10051.

5. INTENDED USE

The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.

6. INDICATION FOR USE STATEMENT

The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.

7. SUBSTANTIAL EQUIVALENCE COMPARISON

In the comparison below, the subject device refers to the SafetiHeel and its private brand devices, MediHeel and Novaplus devices while the predicate device refers to the preamendments device SafetiHeel lancet under FDA listing number D117836.

Similarities/Differences			
Item	**SafetiHeel**	**Predicate Device**	**MediHeel and Novaplus**
FDA Device Listing Number		D117836	
Classification	Class II	Class I	Class I
Product Code	FMK	FMK	FMK

510(k) Summary
SafetiHeel Safety Lancet

Similarities/Differences			
Item	**SafetiHeel**	**Predicate Device**	**MediHeel and Novaplus**
Intended Use	The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.	The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.	The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.
Indication For Use	The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.	The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.	The device is used to obtain capillary blood samples from the heel of newborn and neonatal infants in the healthcare setting by qualified healthcare providers.
Manufacturer	NSP Tech Pte Ltd	NSP Tech Pte Ltd	NSP Tech Pte Ltd
Sterilizer	GrandTen Sdn Bhd	GrandTen Sdn Bhd	GrandTen Sdn Bhd
Appearance			

510(k) Summary
SafetiHeel Safety Lancet

Similarities/Differences			
Item	**SafetiHeel**	**Predicate Device**	**MediHeel and Novaplus**
Product Configuration	Housing Protective Cap Blade Holder Slider Top Cover Roller Slider Left Slider Right Washer Blade Trigger Spring Return Spring	Housing Protective Cap Blade Holder Slider Top Cover Roller Slider Left Slider Right Washer Blade Trigger Spring Return Spring	Housing Protective Cap Blade Holder Slider Top Cover Roller Slider Left Slider Right Washer Blade Trigger Spring Return Spring
Sterilization	Gamma Radiation 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	Meet the Sterility Assurance Level of 10-6 as per the requirement of ISO 11137-1:2006	Meet the Sterility Assurance Level of 10-6 as per the requirement of ISO 11137-1:2006
Use	Single-Use only	Single-Use only	Single-Use only
Bio compatibility	ISO 10993 series	ISO 10993 series	ISO 10993 series
Shelf Life	5 years	5 years	5 years

510(k) Summary
SafetiHeel Safety Lancet

8. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject device SafetiHeel and her private brand devices under names MediHeel and Novaplus has similarities with the predicate device in areas such as Intended Use, Indication For Use, Product Configuration, Material used for its key components and Safety Features. For sterilization, both the subject and predicate device uses the Gamma Radiation Sterilization method with attaining the Sterility Assurance Level (SAL) of 10^{-6}.

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

9. PERFORMANCE TEST COMPARISON

- **Comparison between SafetiHeel and predicate device**

Test	Model	Predicate Device (specification)	SafetiHeel performance
Cutting Depth Test – ability of the blade to keep within cutting depth range when the device is activated	SH-065	0.65 to 0.85 mm	0.63 to 0.80 mm
	SH-085	1.00 to 1.20 mm	1.04 to 1.19 mm
	SH-100	1.40 to 1.60 mm	1.42 to 1.59 mm
	SH-150	1.60 to 1.80 mm	1.66 to 1.79 mm
Trigger Force Test – force required to push the blade out of the housing of the device for incision operation activation	SH-065	450 to 750 grams	475 to 575 grams
	SH-085	450 to 750 grams	494 to 578 grams
	SH-100	450 to 750 grams	496 to 565 grams
	SH-150	450 to 750 grams	494 to 586 grams

510(k) Summary
SafetiHeel Safety Lancet

Test	Model	Predicate Device (specification)	SafetiHeel performance
Blade Retraction Test – the ability of the blade to retract into the housing of the device after completing incision operation	SH-065	The blade of the device must retract into the housing of the device after it has completed the incision operation	The samples of all the models tested show the devices retracting the blade into the housing after completing the incision operation.
	SH-085		
	SH-100		
	SH-150		

- **Comparison between MediHeel and predicate device**

Test	Predicate Device Model	Predicate Device (specification)	MediHeel performance	MediHeel Model
Cutting Depth Test – ability of the blade to keep within cutting depth range when the device is activated	SH-065	0.65 to 0.85 mm	0.67 to 0.81 mm	1003
	SH-085	1.00 to 1.20 mm	1.05 to 1.16 mm	1004
	SH-100	1.40 to 1.60 mm	1.45 to 1.58mm	1005
	SH-150	1.60 to 1.80 mm	1.65 to 1.75 mm	1006
Trigger Force Test – force required to push the blade out of the housing of the device for incision operation activation	SH-065	450 to 750 grams	475 to 588 grams	1003
	SH-085	450 to 750 grams	496 to 591 grams	1004
	SH-100	450 to 750 grams	488 to 585 grams	1005
	SH-150	450 to 750 grams	492 to 596 grams	1006

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SafetiHeel Safety Lancet

Test	Model	Predicate Device (specification)	MediHeel performance	MediHeel Model
Blade Retraction Test – the ability of the blade to retract into the housing of the device after completing incision operation	SH-065	The blade of the device must retract into the housing of the device after it has completed the incision operation	The samples of all the models tested show the devices retracting the blade into the housing after completing the incision operation.	1003
	SH-085			1004
	SH-100			1005
	SH-150			1006

- **Comparison between Novaplus and predicate device**

Test	Predicate Device Model	Predicate Device (specification)	Novaplus performance	Novaplus Model
Cutting Depth Test – ability of the blade to keep within cutting depth range when the device is activated	SH-085	1.00 to 1.20 mm	1.06 to 1.15 mm	10041
	SH-100	1.40 to 1.60 mm	1.44 to 1.57 mm	10051
Trigger Force Test – force required to push the blade out of the housing of the device for incision operation activation	SH-085	450 to 750 grams	492 to 597 grams	10041
	SH-100	450 to 750 grams	486 to 589 grams	10051
Blade Retraction Test– the ability of the blade to retract into the housing of the device after completing incision operation	SH-085	The blade of the device must retract into the housing of the device after it has completed the incision operation	The samples of all the models tested show the devices retracting the blade into the housing after completing the incision operation.	10041
	SH-100			10051

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SafetiHeel Safety Lancet

10. SYNOPSIS OF PERFORMANCE STUDY RESULTS

Performance Test result done on the subject device is compared against the specification of the predicate device in the areas of Cutting Depth and Trigger Force Test.

• **Cutting Depth Test** – ability of the blade to keep within cutting depth range when the device is activated	The subject device is able to push out the Blade when activated and the blade incise within the range of cutting depth as per the specification of the predicate device.
• **Trigger Force Test** – force required to push the blade out of the housing of the device for incision operation activation	The Trigger Force applied on the subject device falls within the specification of the predicate device with the blade being pushed out for the incision operation.
• **Blade Retraction Test** – the ability of the blade to retract into the housing of the device after completing incision operation	The subject device is able to retract the Blade into its housing after it have completed the incision operation.
• **Sterilization Testing**	Sterilization is done for the subject device with reference to ISO 11137-1:2006 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11737-1: 2006 with ISO 11737-2: 2009 to attain a Sterility Assurance Level of 10^{-6}. Dose mapping is carried out with planes representing the minimum and maximum dose location for the subject device. The latter is checked for its sterility after it has undergone the sterilization process.

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Result of the performance tests show the subject device meeting the specification of the predicate device in the Cutting depth and Trigger Force requirement. The subject device is also able to demonstrate its Sharps Injury Prevention feature through the result of the Blade Retraction Test. This shows the subject device's substantive equivalence to the predicate device in the area of device performance.

The result of the sterilization validation process shows that the subject device attaining the requirement of Sterility Assurance Level (SAL) of 10^{-6} similar to the predicate device.

11. PRODUCT SAFETY AND EFFECTIVENESS DATA

Product Safety Design and Effectiveness	The housing of the device encases the Blade preventing any needle stick issue with user or patient before the device is activated. The device also has a protective cap assembled to the housing of the device. This prevents any inadvertent contact with the blade by the user or patient before use. Once the device is activated by pushing the device onto the heel of the patient, the blade is pushed out of the housing by the Trigger Spring. After the device has performed the incision operation, the Return Spring will now push the blade back into the housing avoiding the occurrence of needlestick issue. The Trigger Spring helps in attaining the effectiveness of the device in providing the penetration operation essential for the incision and 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 principle of incising the heel of the newborn and neonatal infants for capillary blood sample collection. The device is first placed on the heel the patient and using contact activation means, the automatic incision mechanism is activated with the blade coming out of the device housing to make the incision. After the incision operation is completed, the blade will automatically retract into the housing. Because of the construction of the mechanism, the blade cannot be pushed out of the housing for a second round of incision preventing the device from being reused. After use, the device is to be discarded in a suitable biohazard container. The incision on the heel for the blood sampling operation is controlled for its depth of the incision. This is done by the design of the parts operating in the device. Hence, the device is checked for Cutting Depth as part of its performance assessment. The pushing out of the blade is controlled by the Trigger Spring encased in the housing of the device. Here, the Trigger Force is measured as part of device performance assessment.

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SafetiHeel Safety Lancet

12. SUBSTANTIAL EQUIVALENCE

The comparison and evaluation of the device features, intended use, indication for use statement, product configuration, safety and effectiveness, materials 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. The physical dimension, appearance, key component, sterilization, packaging used for the subject device are also the same as those of the predicate device.

13. CONCLUSION

From the evaluation above, we can deem that the SafetiHeel , MediHeel and Novaplus are substantially equivalent to the predicate device.