February 13, 2023

Facet Technologies LLC
James Bonds
Director Regulatory Affairs
3900 North Commerce Drive
Atlanta, Georgia 30344

Re: K223370
Trade/Device Name: NeatNick Heel Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: January 10, 2023
Received: January 11, 2023

Dear James Bonds:

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.

Submission Number *(if known)*

K223370

Device Name

NeatNick Heel Safety Lancet

Indications for Use *(Describe)*

The NeatNick Heel Safety Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants for subsequent diagnostic testing.

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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K223370

NeatNick Heel Safety Lancets

510(k) Summary

(Reference 21 CFR 807.92)

Submitted by:	Facet Technologies, LLC 3900 North Commerce Drive Atlanta, GA 30344-8149 Phone Number: (770) 590-6462 Fax Number: (770) 590-6412
Contact:	James R. Bonds
Date of Preparation:	October 17, 2022
Device Trade Name:	NeatNick Heel Safety Lancets
Common Name:	Blood Lancet
Classification Name:	Single use only blood lancet with an integral sharps injury prevention feature
Regulation:	878.4850
Product codes:	FMK (Single use only blood lancet with an integral sharps injury prevention feature)
Product Classification:	II
Panel:	General & Plastic Surgery
Predicate Device:	NeatNick Heel Safety Lancet (Product Code FMK, 510(k) Exempt)

Device Description

The NeatNick Heel Safety Lancet is a single use, blood sampling device with a sterile blade that are used by medical professionals to obtain a blood sample from the feet of neonates and infants for diagnostic purposes. The NeatNick Lancet incorporates an integral sharps injury prevention feature that also prevents reuse of the lancet.

The NeatNick Lancet has been in commercial distribution since 2006.

NeatNick Lancets are available in two configurations (Preemie and Full Term) are intended to be used by medical professionals to obtain a blood sample for diagnostic testing. The lancets consist of a stainless steel blade overmolded with low density polyethylene (LDPE) which protects the blade until use and functions as a sterile barrier. The lancet is single use, disposable and is sterilized by gamma radiation to a SAL of 10^{-6}.

Biocompatibility testing has been conducted per ISO 10993 at a GLP testing facility. The lancet is classified as Class II.

The lancet is currently in commercial distribution in the United States and Canada. Since commercial distribution of the current lancets began, there have been no design changes.

Indication for Use

Indication for Use: The NeatNick Heel Safety Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants for subsequent diagnostic testing.

Technological Characteristics

The primary technological characteristics and intended use of the NeatNick Heel Safety Lancetss are the same as the identified predicate devices.

As indicated in Table 1, the NeatNick Heel Safety Lancet is substantially equivalent to characteristics of the identified predicate device, the NeatNick Heel Safety Lancet previously marketed as a 510(k) exempt device.

Table 1: Comparison of Subject Device and Predicate Device

Characteristic	Predicate Device	Subject Device
Indication for Use	The NeatNick Heel Safety Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants for subsequent diagnostic testing.	Same
Intended Use	The NeatNick Heel Safety Lancet is intended for use by medical professionals to obtain a sample of blood from neonates and infants for subsequent diagnostic testing. The device is for use only on a single patient. The NeatNick Heel Safety Lancet is a disposable, single use device. The device incorporates a spring-actuated sterile sweeping action blade that automatically retracts into the device housing after deployment and renders the device inoperable thereafter.	Same
Manufacturer	Facet Technologies, LLC	Same
510(k) Number	N/A	
Product Code	FMK	Same
Trigger/spring material	Tenac 7010 acetal (polyoxymethylene homopolymer)	Same
Blade material	Type 301 stainless steel	Same
Trigger actuation force	8N-36N	Same
Length of cut	Full term: 2.9mm-4.1mm Preemie: 1.8mm-3.0mm	Same
Depth of cut	Full term: 1.0mm-1.5mm Preemie: 0.65mm-1.25mm	Same
Body Material	High impact polystyrene (HIPS)	Same

Characteristic	Predicate Device	Subject Device
Biocompatibility	Conforms to ISO10993-1	Same
Blade Sterility	Sterilized by Gamma Radiation SAL = 10^{-6}	Same

Non-clinical Testing Summary and Conclusions

Non-clinical bench testing was performed to ensure predetermined criteria were met and the special controls (21 CFR 878.4850) were satisfied. This includes mechanical design verification and validation testing in order to ensure the risks were appropriately managed in addition to verifying that the mechanical functions of the device are suitable for use over the shelf life of the device.

Clinical testing is not applicable as the risk analysis confirmed that all identified risks were addressed and mitigated appropriately. Residual risks after mitigation were acceptable. There were no special performance of safety concerns identified.

In summary, the results of nonclinical testing demonstrate that the candidate device is substantially equivalent to the predicate device.

Conclusion

The intended use, technology, non-clinical testing, and functionality of the NeatNick Heel Safety Lancets demonstrate a substantially equivalent safety and effectiveness profile to the predicate device and should perform as well as the predicate in the specified use conditions.