February 22, 2024

Drawbridge Health, Inc.
Beth Thompson
Sr. Regulatory Consultant, Lean RAQA
5949 Amberwood Dr.
Naples, Florida 34110

Re: K223826
Trade/Device Name: NanoDrop Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: January 26, 2024
Received: January 29, 2024

Dear Beth Thompson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.02.22 13:18:38 -05'00'

Mark Trumbore, 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)*
K223826

Device Name
NanoDrop Lancet

Indications for Use *(Describe)*
The NanoDrop Lancet is intended for use to obtain a capillary blood sample. It does not collect or transport such samples.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. APPLICANT INFORMATION

Submitter Information	
Company Name:	Drawbridge Health, Inc
Address:	620 Omni Industrial Blvd Summerville, SC 29486
Phone Number:	1-631-897-5215
Establishment Registration Number	3015798231
Primary Company Contact	
Name:	Jerome Scelza
Title:	Co-CEO
Phone Number:	1-631-897-5215
Email:	jscelza@dbhealth.com
Official Correspondent	
Name:	Beth Thompson
Title:	Sr. Regulatory Consultant
Phone Number:	1-224-656-3620
Email:	betht@leanraqa.com

2. DATE OF PREPARATION

Date of Preparation	January 26, 2024

3. DEVICE INFORMATION

Device Name:	NanoDrop Lancet device
Common Name:	Blood Lancet
Classification Name:	Single use only blood lancet with an integral sharps injury prevention feature
Model(s):	FD004
Regulation Number:	21 CFR 878.4850(a)
Product Code:	FMK
Class:	Class II

4. PREDICATE DEVICES

Predicate Type	510(k) Number	Name of Device	Name of Manufacturer
Primary Device	K223208	Safety Lancet	Suzhou Zhenwu Medical Co., Ltd.
Reference Device	K220643	DropSafe Acti-Lance Safety Lancet	HTL-Strefa S.A.

5. DEVICE DESCRIPTION

The Drawbridge Health NanoDrop Lancet Device is a sterile, single-use, disposable lancet for capillary blood sampling. The device incorporates two (2) stainless steel needles with blade tips to make two (2) small incisions in the skin. The device is made of a gray plastic housing base that has a molded outer rim and a bowl-shaped cavity. The outer rim is covered by a hydrogel-adhesive to better attach the device to the skin, with a cover over the hydrogel adhesive pad for its protection. The bowl shape provides space for the skin to be drawn up as slight controlled vacuum pressure is applied, and for the needle blades to access the skin after piercing through a septum and vacuum chamber foil. There are two (2) clearly marked gray push buttons on the device:

- The gray button marked "I" is for activation of the vacuum; and
- The gray button marked "II" is for deployment of the needle blades.

There is a yellow removable plastic locking feature to prevent accidental activation of the button that deploys the needle blades(gray button marked "II"). There is also a white vacuum chamber lid securely attached on top of the base, over the gray lancet enclosure, where the two needle blades are held in a clear plastic needle holder, along with the main spring and retraction spring, and into which they automatically retract after use, with no access to this gray lancet enclosure possible. This prevents the lancet from being used more than once, and it keeps the blades retracted for sharps injury prevention safety and for disposal. A permanent plug obstructs the port and mitigates unintended connection of a collection container.

The single model number is FD004.

6. INDICATIONS FOR USE

The NanoDrop Lancet device is intended for use to obtain a capillary blood sample. It does not collect or transport such samples.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Device	Subject Device	Predicate Device	Remark	Reference Device	Discussion
Device	Blood Lancet	Blood Lancet	Same	Blood Lancet	Same
Manufacturer	Drawbridge Health, Inc	Suzhou Zhenwu Medical Co.	Different	HTL-Strefa S.A.	Different
510(k) Number	K223826	K223208	Different	K220643	Different
Product Code	FMK	FMK	Same	FMK	Same
Classification	Class II	Class II	Same	Class II	Same
Intended Use	Intended for capillary blood sampling	Intended for capillary blood sampling	Same	Intended for capillary blood sampling	Same

Intended Population	Adults and Pediatrics. If user is under the age of 18, the lancet must be used by an adult or under the supervision of an adult	Adults and Pediatrics. If user is under the age of 18, the lancet must be used by an adult or under the supervision of an adult	Same	Not stated	N/A
Number of Uses	Single use on one person; no more than one use	Single use on one person; no more than one use	Same	Single use on one patient	Same
Prescription or OTC Use	Over-the-counter	Over-the-counter	Same	Over-the counter	Same
Needle Blade gauge	17G blades	Available in 21G and 18G blades	Similar	17G blades	Same
Needle Blade Diameter	0.060in +/- 0.001in (1.52mm +/- 0.025mm)	21G: 0.800mm-0.830mm 18G: 1.200mm-1.300mm	Similar	Not stated	N/A
Needle Blade Length	0.500in +/- 0.002in	Unknown	Unknown	Not stated	N/A
Needle Blade Penetration Depth	1.9-2.0 mm	21G: 1.8, 2.0, 2.2, 2.4 mm 18G: 2.0, 2.2, 2.4 mm	Similar	Not stated	N/A
Usage	Single use only	Single use only	Same	Single use only	Same
Sterilization	Gamma radiation	Gamma radiation	Same	ISO 10993	Same
Sharps Injury Prevention Feature	Only one puncture can be made after the protective lock and adhesive cover are removed and the push buttons are activated to start the vacuum and to release the blades. Both lancet blades automatically retract into the device after activation.	The puncture function can only be used after the cap is pulled off. Lancet retracts into the device after activation.	Similar	Sharps Injury Prevention Feature and Blade Retraction	Similar
Biocompatibility	No cytotoxicity No irritation No skin sensitization No acute systemic toxicity No pyrogens	No cytotoxicity No irritation No skin sensitization No acute systemic toxicity No pyrogens	Same	ISO 10993	Same
Clinical Testing	Safety and Performance study	None	Different	None	Different
Shelf life	19 months	5 years	Similar	5 years	Similar

The characteristics of the devices present no material differences in substantial equivalence as the gauge size and number of blades does not affect performance, the difference in method of activation does not affect performance, the penetration depth falls within the range of the predicate device, and the difference in shelf life does not affect performance. The devices are substantially equivalent to each other.

8. PERFORMANCE TESTING

8.1 Non-clinical performance

The following performance testing met all acceptance criteria.

- Pain levels and preferred method of obtaining blood - User Study
- Lancet Cut (Penetration) Depth
- Applied Vacuum Lower Bound Test
- Lancet Needle Blade Diameter
- Device Length and Width
- Device Redeployment Testing
- Lancet Retraction Distance
- Pull Force Testing of Needle from Holder
- Sharps Injury Prevention Feature Drop Testing
- Pull Force and Mechanical Testing of Permanent Plug
- Permanent Plug Leak Test
- Hydrogel Ring and Bloodborne Pathogen Barrier
- USP-NF: 2020 Chapter ‹788› Testing for Particulates in Solutions or Medical Devices

8.2 Biocompatibility

The following biocompatibility testing was successfully completed:

10993-1: 2009	ISO	Biological Evaluation of Medical Devices-Part 1 : Evaluation and testing within a risk management process
10993-3: 2014	ISO	Biological Evaluation of Medical Devices- Part 3 : Tests for genotoxicity, carcinogenicity, and reproductive toxicity
10993-4: 2006	ISO	Biological Evaluation of Medical Devices-Part 4 : Selection of tests for interaction with blood
10993-5: 2009	ISO	Biological Evaluation of Medical Devices-Part 5 : Test for *invitro* cytotoxicty
10993-10: 2010	ISO	Biological Evaluation of Medical Devices-Part 10 : Test for irritation and skin sensitization
10993-11:2006	ISO	Biological Evaluation of Medical Devices-Part 11 : Test for systemic toxicity; Material-mediated Pyrogenicity
USP-NF 2018	USP ‹161›	USP Limulus Amebocyte Lysate (LAL) Test - Kinetic-Turbidimetric Method

8.3 Sterilization/Shelf-life Testing/Shipping Testing

Sterilization Method	Radiation (electron beam)

Sterility Assurance Level	SAL 10^{-6}

11137-1:2006/(R)15; A1:2013	ANSI/AAMI/ISO	Sterilization of Healthcare Products-Radiation-Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices
11137-2: 2013	ANSI/AAMI/ISO	Sterilization of Healthcare Products-Radiation-Part 2 : Establishing the radiation dose
11137-3: 2017	ANSI/AAMI/ISO	Sterilization of Healthcare Products-Radiation-Part 3 : Guidance on dosimetric aspects
F1980-16	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
4169-16	ASTM	Standard Practice for Performance Testing of Shipping Containers and System
F2096-11	ASTM	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (bubble test)
F88/F88M-15	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials

8.4 Animal and Clinical performance data

No animal study is included in this submission.

A clinical study was performed with the aim to evaluate the safety and use of the NanoDrop Lancet Device and to evaluate the user's opinion with regards to handling characteristics of the device as compared to a comparable cleared OTC FMK fingerstick lancet (Acti-Lance K220643). The study included thirty subject with two samples for each device (four samples per subject). All acceptance criteria were met, supporting safe and effective use of the NanoDrop Device unsupervised and self-administered by adults on the upper arm.

9. CONCLUSION

The conclusions drawn from the clinical and nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device. They are substantially equivalent to each other.