February 24, 2023

Alex Garrett
Regulatory Affairs Specialist
747 West 4170 South
Murray, Utah 84123

Re: K223900
Trade/Device Name: babyLance Safety Heelstick (BLM, BLN, BLP)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: December 15, 2022
Received: December 28, 2022

Dear Alex Garrett:

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

Indications for Use

510(k) Number (if known): K223900

Device Name: babyLance® Heel Incision Device

Indications for Use:

The babyLance safety heelstick is a single-use incision device used to obtain a blood sample from the heel of a neonate or infant. babyLance has a sharps prevention feature to protect the user from a needlestick injury.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(5) 510(k) Summary

Manufacturer Name	Clinical Innovations, LLC
Manufacturer Address	747 West 4170 South, Murray, UT 84123, USA
Manufacturer contact information	P. 801-268-8200 Toll Free: 888-268-6222 https://www.clinicalinnovations.com
510(k) Number	TBD
Contact Person	Alex Garrett Regulatory Affairs Specialist agarrett@laborie.com
Preparation Date	16-DEC-2022
Trade Name	babyLance Safety Heelstick Device
Common Name	Disposable Safety Lancet
Classification Name	Single Use Only Blood Lancet With An Integrated Sharps Injury Prevention Feature (21 CFR 878.4850, Product Code FMK)
Predicate	BabyLance Heel Incision Device, 510K number K130132

Device Description

The babyLance™ safety heelstick is a sterile, single-use device designed to be a one-handed, automated incision device for use in heel sticks of newborn and neonatal infants (also called preemie infants). A heel stick is a procedure in which a newborn baby's heel is pricked for blood collection for use in newborn screening tests.

The babyLance™ is constructed with a Nylon housing which holds the stainless-steel cutting blade and deployment mechanism. The babyLance™ has a sharps prevention feature to protect the user from a sharps injury. It is supplied in a sterile polypropylene tray with a Tyvek™ lid.

The outside plastic casing is designed to be ergonomic for the user and compatible with an infant's foot. The user breaks off the trigger lock from the device, the device is positioned on the newborn's heel and the user depresses the trigger to activate the blade to make an incision. Once the blade has been triggered, the blade is automatically retracted within the housing. The device is discarded in a sharps container after use.

Table 1: Device Variants

BabyLance	Product Code	Body/Trigger Colors
Micro preemie	BLM	Yellow/Lime Green
Preemie	BLP	Pink/White
Newborn	BLN	Blue/Green

Indications for Use

As provided in the Instructions for Use (IFU) (See Appendix I), for babyLance Safety Heelstick Device:

The babyLance safety heelstick is a single-use incision device used to obtain a blood sample from the heel of a neonate or infant. babyLance has a sharps prevention feature to protect the user from a needlestick injury.

Contraindications

As provided in the IFU (See Appendix I), for babyLance Safety Heelstick Device, the device is not to be used in the following conditions:

- Presence of local edema
- Puncturing previously traumatized skin in the same location
- Presence of cyanosis or impaired perfusion
- Puncturing the calcaneus
- Infection at the site

Patient Population

babyLance Safety Heelstick Devices are to be used on newborns and premature infants.

Predicate Comparison

Materials, Principals of Operation, Indications for Use Contraindications and Patient Population for babyLance are the same as the predicate device.

Table 2: Substantial Equivalence Comparison Table

Technological Characteristics	**babyLance (predicate)**	**babyLance (device under review)**
Clearance Date	February 11, 2013	TBD
510(k) number	K130132	TBD
510(k) submitter	MediPurpose Pte. Ltd. 15 Hoe Chiang Road #12-02 Tower Fifteen Singapore, SINGAPORE 089316	Clinical Innovations, LLC 747 West 4170 South, Murray, UT 84123, USA
Intended Use	The babyLance is an incision device to obtain a blood sample from the heel of newborn and preemie infants. The babyLance has a sharps prevention feature to protect the user from a sharps injury.	Intended to be used by trained healthcare professionals to draw a blood sample from the heel of a neonate or infant.
Indications for Use	The babyLance is an incision device to obtain a blood sample from the heel of newborn and preemie infants. The babyLance has a sharps prevention feature to protect the user from a sharps injury.	The babyLance safety heelstick is a single-use incision device to obtain a blood sample from the heel of a neonate or infant. babyLance has a sharps prevention feature to protect the user from a needlestick injury.
Product Code	FMK	Same

Panel	General & Plastic Surgery	Same
Classification	Class I	Class II
Regulation	21 CFR 878.4400	21 CFR 878.4850
Patient Population	Newborn, Premature Infants	Same
Principals of Operation	The stainless-steel blade is deployed by removing the trigger lock and pressing a spring-loaded trigger. The principals involved in the operation of this device are all principles of mechanical energy.	Same
Labeling	Individual Tyvek label, Secondary box label, Tertiary shipping box Label.	Same. See Section 13 for device labeling.
Design	ABS housing containing stainless steel blade activated by a trigger. Blade retracts into housing after incision is made.	Same
Mechanical Specifications		
Overall Size	Length: 1.25 in (3.2 cm) Height; 1.25 in (3.2 cm)	Same
Cut Profile "Micro Preemie"	N/A	Length: 2.2 mm Depth: 0.60 mm
Cut Profile "Preemie"	Length: 2.89 mm Depth: 0.86 mm	Length: 3.0 mm Depth: 0.85 mm
Cut Profile "Newborn"	Length: 3.01 mm Depth: 1.08 mm	Length: 3.0 mm Depth: 1.00 mm
Material Composition		
Blade (blood contact)	304 Stainless Steel	Same
Housing/Case (heel contact)	High Density Polyethylene (HDPE)	Same
Trigger (no patient contact)	Acrylonitrile Butadiene Styrene (ABS)	Same
21 CFRLatex content	Latex Free	Same
Chemical Composition	N/A	N/A
Energy Source	N/A	N/A
Safety Features		
Sharps Injury Prevention Passive Feature	1. Remove trigger lock	Same
	2. Blade exits the housing only during use, spring driven, activated by trigger.	Same
	3. Lancet will automatically retract at the end of incision motion.	Same
Prevention of Tip Exposure	Blade is not exposed except when device is used against the infant's heel.	Same
Automatic Lancet Retraction After Use	When device is used, the end of the incision motion retracts and locks the blade back into the housing.	Same
Prevention of Lancet Reuse	The blade retracts back into the housing at the end of the incision motion; the internal locking mechanism locks the blade in the housing.	Same
Use Condition Provided	Sterile, Single Patient Use	Same
Sterilization Method	Gamma Irradiation	Same
SAL	10^{-6}	Same

Shelf-life	4 Years	Same
Biocompatibility Profile	"External Communicating Device" with Tissue/Bone/Dentin contact with limited patient exposure (<24 hour)	Same
Biocompatibility (ISO 10993-1)	Cytotoxicity – not cytotoxic Sensitization – no evidence of causing sensitization Irritation – no evidence of causing irritation	

Biocompatibility

According to ISO 10993-1:2018 Biocompatibility compliance assessment, the device was assessed to be "External Communicating Device" with Tissue/Bone/Dentin contact with limited patient exposure (<24 hour).

Biocompatibility testing has been performed on finished product materials, which are in contact with the human body, in accordance with ISO 10993 Part 1: Biological Evaluation of Medical Device. The results of this pre-clinical testing indicate that the materials met the test requirements as specified and that based on the results of the testing performed, the device is considered appropriate from a biological and toxicological perspective for its intended use in all patient populations.

Physical Characterization

babyLance Safety Heelstick Device has completed the applicable physical characterization and verification. This testing included: Biocompatibility, Stability, Shelf-Life, Shipping, Usability, Simulated Use and User Validation.

Substantial Equivalence

The babyLance Safety Heelstick device has the same principles of operation, intended use, and technological characteristics as the predicate device. The minor differences do not raise any issues of safety or effectiveness. Testing results support the determination of substantial equivalence with the results demonstrating that the babyLance Safety Heelstick has equivalent results as the predicate device.