11/02/2022

Asahi Polyslider Co., Ltd.
% Stuart Goldman
Sr. Consultant, RA/QA
Emergo by UL
2500 Bee Cave Road
Bldg. 1, Suite 300
Austin, Texas 78746

Re: K222084
Trade/Device Name: OneTouch Delica Safety, HemoCue Safety Lancet, Assure Lance and Assure Lance Plus, Capiject Safety Lancet, Heel Lancet Newborn, Heel Lancet Preemie
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class II
Product Code: FMK
Dated: September 26, 2022
Received: September 29, 2022

Dear Stuart Goldman:

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)*
K222084

Device Name
OneTouch® Delica® Safety, HemoCue® Safety Lancet, Assure® Lance, Assure® Lance Plus

Indications for Use *(Describe)*
OneTouch® Delica® Safety is a single use blood lancet with sharps prevention feature to protect the user from a needlestick injury and that is intended for capillary blood sampling from a fingertip.

HemoCue® Safety Lancet is single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury.

Assure® Lance Safety Lancets are single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury.

Assure® Lance Plus Safety Lancets are single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury.

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."

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)*
K222084

Device Name
Capiject® Safety Lancet, Heel Lancet Newborn, Heel Lancet Preemie

Indications for Use *(Describe)*
Capiject® Safety Lancet is single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury.

Heel Lancet Newborn is single use and intended for capillary blood sampling from a heel for newborn. Sharps prevention feature protects the user from needlestick injury.

Heel Lancet Preemie is single use and intended for capillary blood sampling from a heel for preemie. Sharps prevention feature protects the user from needlestick injury.

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."

510(k) Summary
Single Use Blood Lancets
K222084

1. Submission Sponsor

Asahi Polyslider Company, Ltd.
860-2 Misaki, Maniwa
Okayama 719-3226
Japan
Yoshitaka Akagi
Sr. Manager, Quality Assurance
0867-42-1171

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Stuart R. Goldman
Sr. Consultant
(512) 327-9997

3. Date Prepared

November 2, 2022

4. Device Identification

Trade/Proprietary Name:	Single Use Blood Lancets (OneTouch® Delica® Safety, HemoCue® Safety Lancet, Assure® Lance Safety Lancets, Assure® Lance Plus Safety Lancets, Capiject® Safety Lancet, Heel Lancet Newborn and Heel Lancet Preemie)
Common/Usual Name:	Blood lancets
Classification Name:	Blood lancets
Regulation Number:	878.4850
Product Code:	FMK
Class:	II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate and Reverence Devices

Predicate Device

Device name:	SurgiLance® Safety Lancet
510(k) number:	K101145
Manufacturer:	MediPurpose

Reference Devices

Device name:	OneTouch® Delica® Plus Lancing System
510(k) number:	K221546
Manufacturer:	Asahi Polyslider
Device name:	Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet
510(k) number:	K192666
Manufacturer:	Promisemed Hangzhou Meditech
Device name:	Accu-Chek Safe-T-Pro Uno Lancing Device
510(k) number:	K220364
Manufacturer:	Roche Diabetes Care

6. Indication for Use Statements

OneTouch® Delica® Safety	OneTouch® Delica® Safety is a single use blood lancet with sharps prevention feature to protect the user from a needlestick injury and that is intended for capillary blood sampling from a fingertip. **OTC**
HemoCue® Safety Lancet	HemoCue® Safety Lancet is single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury. **OTC**
Assure® Lance	Assure® Lance Safety Lancets are single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury. **OTC**
Assure® Lance Plus	Assure® Lance Plus Safety Lancets are single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury. **OTC**
Capiject® Safety Lancet	Capiject Safety Lancet is single use and intended for capillary blood sampling from a fingertip. Sharps prevention feature protects the user from needlestick injury. **Rx**
Heel Lancet Newborn	Heel Lancet Newborn is single use and intended for capillary blood sampling from a heel for newborn. Sharps prevention feature protects the user from needlestick injury. **Rx**
Heel Lancet Preemie	Heel Lancet Preemie is single use and intended for capillary blood sampling from a heel for preemie. Sharps prevention feature protects the user from needlestick injury. **Rx**

7. Device Description

The Single Use Blood Lancets are hand-held, sterile, needle or blade-like devices with a pull-off or twist-off cap and integral sharps injury prevention feature for controlled skin puncture to obtain a capillary blood specimen; typically at the fingertip or heel of the patient. The housing of the devices are made of plastic and have a spring-loaded mechanism which enables the tip of the needle or blade to puncture the

fingertip or heel to a predetermined depth, whereby blood is subsequently squeezed out of the puncture site. These devices are made available in various needle and blade sizes which are distinguished by their different colors. Until activation, the lancet is contained within its housing (holder). Immediately after use, the needle or blade is automatically retracted back into its holder until the device is disposed of in an appropriate manner.

8. Substantial Equivalence Discussion

Table 5-1 compares the Single Use Blood Lancets to the predicate device with respect to its intended use, and technological characteristics, forming the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5-1 – Substantial Equivalence Comparison of Blood Lancets to Predicate Device

Attribute	Subject Device	Predicate Device	Reference Device for Lancet Penetration Depth
Manufacturer	Asahi Polyslider	MediPurpose	Roche
510(k) #	Pending	K101145	K220364
Product Codes	FMK	FMK	FMK
Device Name	Single Use Blood Lancets	SurgiLance® Safety Lancets	Accu-Chek Safe-T-Pro Uno Lancing Device
Device Description	The needle or blade lancet is used to prick a test site to draw a sample of blood for testing purposes. Once fired, the needle or blade is safely retracted into its plastic housing that acts as a sharps prevention feature until the device is disposed. The device is provided single use and sterile.	The needle or blade lancet is used to prick a test site to draw a sample of blood for testing purposes. Once fired, the needle or blade is safely retracted into its plastic housing that acts as a sharps prevention feature until the device is disposed. The device is provided single use and sterile.	
Intended Use	For the hygienic collection of capillary blood for testing purposes.	For the hygienic collection of capillary blood for testing purposes.	
Type of Use	Rx and OTC	Rx and OTC	
Mechanism of Action	Spring-loaded mechanism which enables the tip of the sterile lancet to puncture to a predetermined depth.	Same as subject devices.	

Attribute	Subject Device	Predicate Device	Reference Device for Lancet Penetration Depth
Load and Firing	Loading / priming the device is not required. Press release button or trigger to activate lancet mechanism or press device down against test site to activate lancet mechanism.	Loading / priming the device is not required. Press device down against test site to activate lancet mechanism.	
Lancet Sizes / Dimensions	30G (needle) / ø 0.32mm 28G (needle) / ø 0.4mm 25G (needle) / ø 0.5mm 23G (needle) / ø 0.65mm 21G (needle) / ø 0.8mm 1.5mm (blade) 1.75mm (blade) 2.50mm (blade)	28G (needle) 21G (needle) 18G (blade)	28G (needle)
Lancet Sizes / Penetration Depth	30G (needle) / 0.7, 1.5mm 28G (needle) / 1.0, 1.25mm 25G (needle) / 1.1, 2.0mm 23G (needle) / 2.0, 2.25mm 21G (needle) / 1.80mm 1.5mm / 1.00, 1.5, 2.0mm 1.75mm / 0.85mm 2.50mm / 1.00mm	28G (needle) / 1.7mm 21G (needle) / 1.0, 1.8, 2.2, 2.8mm 18G (blade) / 1.8, 2.3mm	28G (needle) / 1.5mm
Needle	Stainless Steel.	Stainless Steel.	
Housing	Polymer.	Polymer.	
Anatomical Site(s)	Fingertip and Heel.	Fingertip.	
Sharps Injury Prevention	Yes, automatic retraction of the needle/blade into plastic device housing.	Yes, automatic retraction of the needle/blade into plastic device housing.	
Sterile	Yes (gamma radiation).	Yes (gamma radiation).	
Single-Use	Yes.	Yes.	
Shelf-Life	5 years.	4 years.	

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the Single Use Blood Lancets and to show substantial equivalence to the predicate device, Asahi Polyslider completed the following verification and validation

activities, including non-clinical tests. Results confirm that the design inputs and performance specifications for the subject devices are met. The Single Use Blood Lancets passed all required testing in accordance with internal requirements, national standards, and international standards shown below, supporting their safety and effectiveness and substantial equivalence to the predicate device:

- Materials of Construction – Specifications met
- Visual, Physical and Dimensional Verification – Specifications met
- Functional Testing – Specifications met
- Performance Testing – Specifications met
- Cytotoxicity Testing per ISO 10993-5 – Passed
- Sensitization Testing per ISO 10993-10 – Passed
- Irritation per ISO 10993-10 – Passed
- Sterilization Validation per ISO 11137-1/-2 – Demonstrates SAL 10^{-6}
- Product Sterility per ISO 11737-1 – Demonstrates product is free of microorganisms
- Shelf-life Testing per ASTM F1980 – Supports a shelf-life of 5 years
- Transportation Testing per ASTM 4169 – Demonstrates package integrity is maintained
- Risk Analysis per ISO 14971 – Hazards identified, ranked and risk mitigation measures implemented

10. Substantial Equivalence Conclusion

The Single Use Blood Lancets have the same intended use as the SurgiLance® Safety Lancets and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the subject device is as safe and effective as the predicate device. Therefore, the Single Use Blood Lancets are substantially equivalent to the predicate device.