August 23, 2022

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

Re: K221546
Trade/Device Name: OneTouch Delica Plus Lancing System
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: May 25, 2022
Received: May 27, 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)*

Device Name
OneTouch® Delica® Plus Lancing System

Indications for Use *(Describe)*
The OneTouch® Delica® Plus lancets are sterile, single use devices that have been designed for single patient use by lay users in a home or general environment. Their intended use is for performing skin punctures on patients for the purpose of obtaining capillary blood samples from the fingertips. The OneTouch Delica Plus lancets are compatible with the single patient use OneTouch® Delica® Plus lancing device.

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
OneTouch® Delica® Plus Lancing System

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

July 21, 2022

4. Device Identification

Trade/Proprietary Name:	OneTouch® Delica® Plus Lancing System
Common/Usual Name:	Blood lancets
Classification Name:	Blood lancets
Regulation Number:	878.4850
Product Code:	QRL, QRK
Class:	II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device

Device name:	Accu-Chek Softclix Blood Lancing System
510(k) number:	K214022
Manufacturer:	Roche Diabetes Care, Inc.

6. Indication for Use Statement

The OneTouch® Delica® Plus lancets are sterile, single use devices that have been designed for single patient use by lay users in a home or general environment. Their intended use is for performing skin punctures on patients for the purpose of obtaining capillary blood samples from the fingertips. The

OneTouch Delica Plus lancets are compatible with the single patient use OneTouch® Delica® Plus lancing device.

7. Device Description

The OneTouch® Delica® Plus Lancing System consists of a non-sterile, reusable base blood lancing device that is intended for use on a single patient and is used in conjunction with a sterile, single-use lancet. The lancing device has 13 depth settings. The lancets are made available in size 30G and 33G and are packaged in boxes of 30 and 100 count.

8. Substantial Equivalence Discussion

Table 5-1 compares the OneTouch® Delica® Plus Lancing System to the predicate device with respect to its intended use, indications for use, and technological characteristics and performance, 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 OneTouch® Delica® Plus Lancing System to the Predicate Device

Attribute	Subject Device	Predicate Device
Manufacturer	Asahi Polyslider	Roche
510(k) #	Pending	K214022
Product Codes	QRL/QRK	QRL/QRK
Device Name	OneTouch® Delica® Plus Lancing System	Accu-Chek Softclix Blood Lancing System
Device Description	The OneTouch® Delica® Plus Lancing System consists of the lancing device and compatible lancets to obtain a drop of blood from a fingertip.	The Accu-Chek Softclix Lancing Device uses compatible Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternative sites using the Accu-Chek Softclix Alternative Site Testing (AST) Cap.
Intended Use	For the hygienic collection of capillary blood for testing purposes.	For the hygienic collection of capillary blood for testing purposes.
Indications for Use	The OneTouch® Delica® Plus lancets are sterile, single use devices that have been designed for single patient use by lay users in a home or general environment. Their intended use is for performing skin punctures on patients for the purpose of obtaining capillary blood samples from the fingertips. The OneTouch Delica Plus lancets are compatible with the single patient use OneTouch® Delica® Plus lancing device.	The Accu-Chek Softclix Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.

Attribute	Subject Device	Predicate Device
		This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.
Type of Use	OTC	OTC
Mechanism of Action	Spring-loaded	Spring-loaded
Lancet Sizes (needle diameter)	30G 33G	28G
Depth Adjustments	13 levels	11 levels
Anatomical Site(s)	Fingertip	Fingertip Ball of the hand Upper arm Lower arm
Materials	Lancing device housing: polymer	Lancing device housing: polymer
	Lancet: cap and body (polymer), needle (stainless steel)	Lancet: cap and body (polymer), needle (stainless steel)
Sharps Injury Prevention	Yes (lancing device)	Yes (lancing device)
Sterile	Lancing device: no	Lancing device: no
	Lancet: yes, gamma radiation (SAL = 10^{-6})	Lancet: yes, gamma radiation (SAL = 10^{-6})
Single-Use	Lancing device: no, multiple use	Lancing device: no, multiple use
	Lancet: yes	Lancet: yes
Shelf-Life	Lancing device: (4 years) Lancet: (5 years)	-

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the OneTouch® Delica® Plus Lancing System 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 device are met. The OneTouch® Delica® Plus Lancing System passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its 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
- Cleaning and Disinfection – Specification 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 4 and 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. Clinical Performance Data

No clinical tests were performed.

11. Substantial Equivalence Conclusion

The OneTouch® Delica® Plus Lancing System has the same intended use as the Accu-Chek Softclix Lancing System 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 OneTouch® Delica® Plus Lancing System is substantially equivalent to the predicate device.