October 17, 2022

Arkray, Inc.
% Maddi Myers
Regulatory Affairs and Quality Systems Project Manager
Arkray Factory USA Inc.
5182 West 76th Street
Minneapolis, Minnesota 55439

Re: K221175
Trade/Device Name: Multi-Lancet Device 2, ReliOn Premier Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: April 22, 2022
Received: April 25, 2022

Dear Maddi Myers:

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)*
K221175

Device Name
Multi-Lancet Device 2
Relion Premier Lancing Device

Indications for Use *(Describe)*
The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are reusable lancing devices intended to be used with sterile, single-use compatible lancet blades to obtain a capillary blood sample from the fingertip or alternate sites for blood glucose testing or other tests that require small amounts of blood. The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are intended for single person use only.

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.

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Administrative Information

Applicant's Name and Address	ARKRAY Factory, Inc. 1480 Koji, Konan-cho Koka-shi, Shiga 520-3306 Japan Establishment Registration # 3003422726
Contact Person	Joe Dempsey Regulatory Affairs and Quality Systems Project Manager
Phone	952-746-2622
Fax	952-646-3230
Email	dempseyj@arkrayusa.com

Regulatory Information

Trade Name	Multi-Lancet Device 2, ReliOn Premier Lancing Device
Classification Name	Multiple Use Blood Lancet For Single Patient Use Only
Common Name	Blood Lancet
Product Code	QRL
Classification Panel	79 – General & Plastic Surgery
Device Classification	21 CFR § 878.4850

Predicate Device Information

Predicate Device Name	Predicate Device 510(k) Number
Accu-Chek Softclix Blood Lancing System	K214022

Device Description

The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are used with a compatible single-use lancet to puncture the skin and release a small amount of blood. The products are distributed individually or packaged together with blood glucose monitoring systems to allow users to obtain capillary whole blood samples required for testing blood glucose levels.

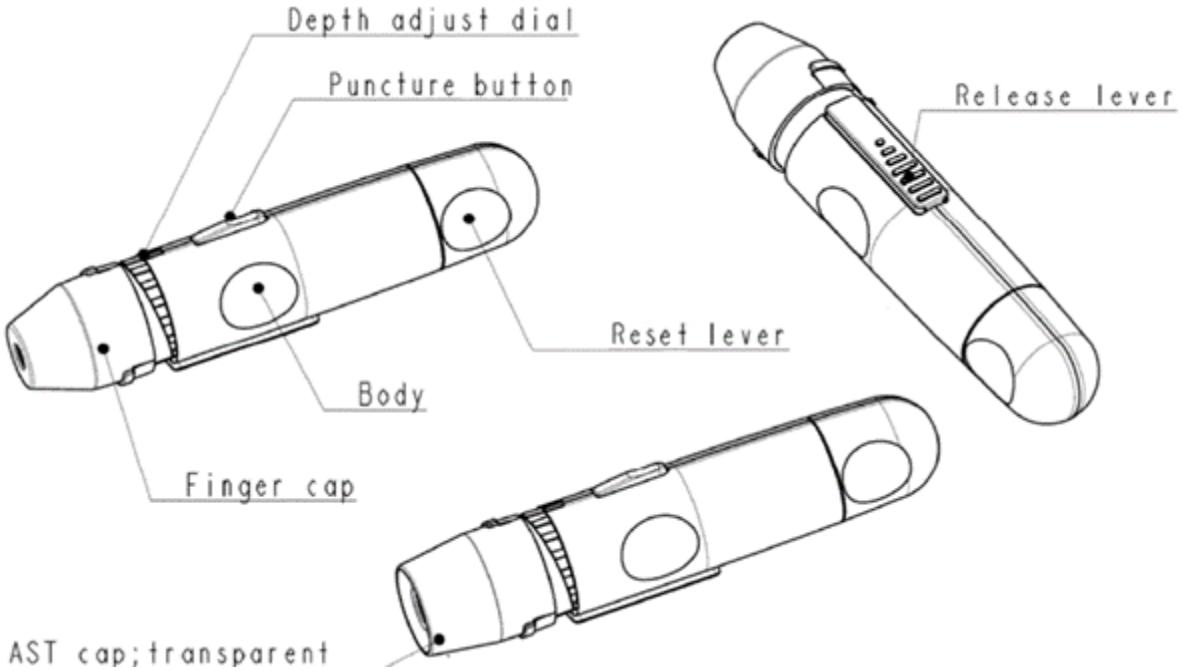

Figure 1: Device Design Image

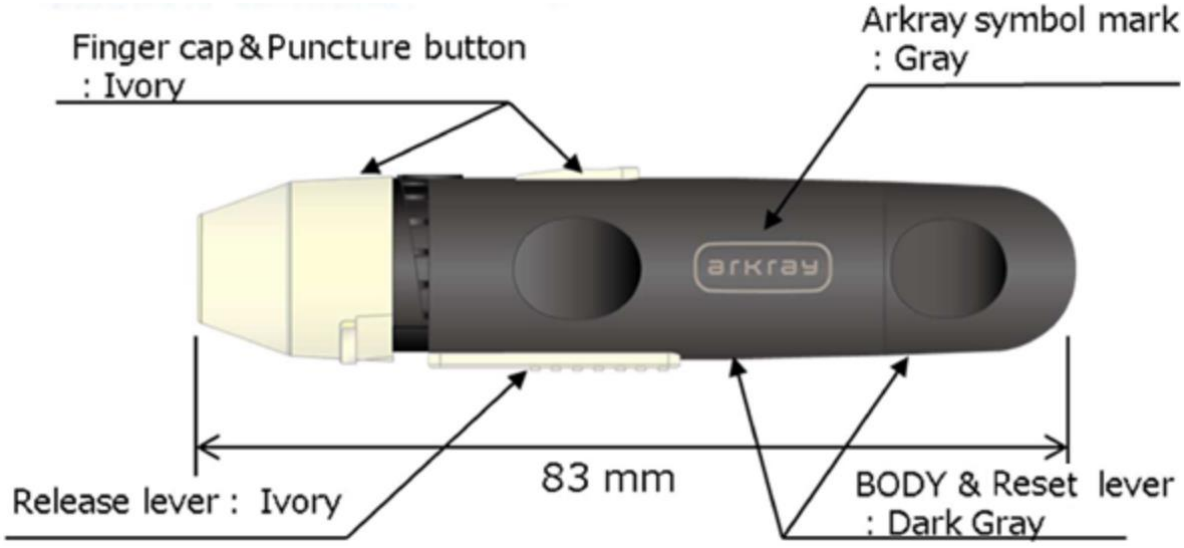

Figure 2: Multi-Lancet Device 2 Color Design Image

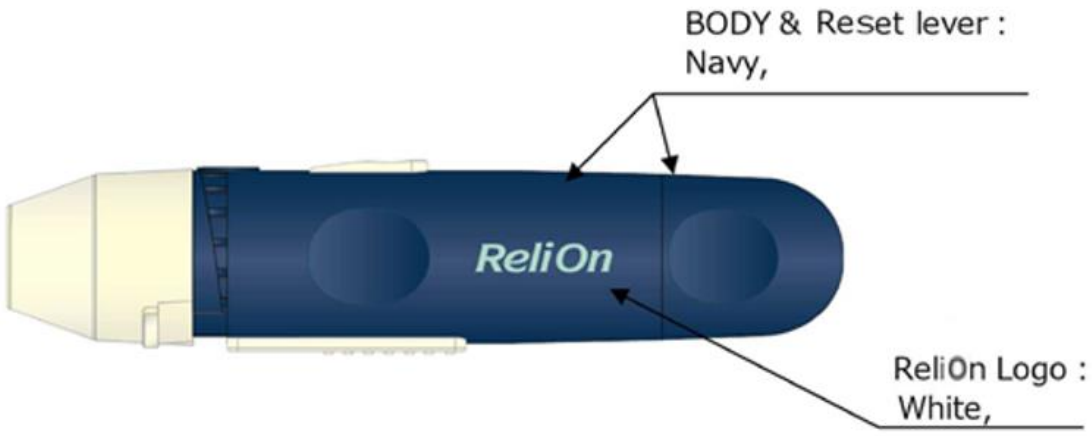

Figure 3: ReliOn Premier Lancing Device Color Design Image

Figure 4: Image of Multi-Lancet Device 2 with AST Cap

Indications for Use

The Multi-Lancet™ Device 2 and ReliOn Premier Lancing Device are reusable lancing devices intended to be used with sterile, single-use compatible lancet blades to obtain a capillary blood sample from the fingertip or alternate sites for blood glucose testing or other tests that require small amounts of blood. The Multi-Lancet™ Device 2 and ReliOn Premier Lancing Device are intended for single person use only.

Substantial Equivalence Information

The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are substantially equivalent to the Accu-Chek Softclix Blood Lancing System. Below **Table 1** provides a comparison between the Multi-Lancet Device 2 and ReliOn Premier Lancing Device and the predicate device.

The Multi-Lancet Device 2 includes the thigh and calf as additional anatomical testing sites when compared to the predicate device. These anatomical testing sites were previously cleared under submission K120759.

Table 1: Similarities and Differences Between Proposed and Predicate Device

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Blood Lancet		
510(k) Number	To Be Determined	K214022
Device Description	The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are used with compatible single-use lancets to obtain a drop of blood from a fingertip using the Finger Cap or alternative sites using the Alternative Site Testing (AST) Cap.	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	The Multi-Lancet™ Device 2 and ReliOn Premier Lancing Device are reusable lancing devices intended to be used with sterile, single-use compatible lancet blades to obtain a capillary blood sample from the fingertip or alternate sites for blood glucose testing or other tests that require small amounts of blood.	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.

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Indications for Use	• The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are intended for single person use only.	• 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. • 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.
Number of Uses	Base (lancing device): multiple use	Base (lancing device): multiple use Lancet: single use
Device Images	Lancing Device with Finger Cap:  Lancing Device with AST Cap:  ReliOn Premier Lancing Device:  	Lancing Device (and AST Cap): 
Depth Adjustment	7 settings by twisting cap	11 settings by twisting cap

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Lancing Depth Range	0.0-3.0mm	0.8-2.3mm
Mechanical Loading	Spring-driven	Spring-driven
Load and firing	After removing the cap, load the lancet into the base. This sets the device and readies it for firing. Fire by pressing the puncture button on the side.	Load by pressing priming button when lancet is inserted Fire by pressing the release button
Reset Method	Firing mechanism is reset by pulling the reset lever.	Firing mechanism is reset by pushing the priming button.
Anatomical sites	• Fingertip • Palm • Forearm • Thigh • Calf	• Fingertip • Ball of the band (palm) • Upper arm • Lower arm (forearm)
Sharps Injury Prevention	Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. The eject lever can then be slid forward for contactless disposal of the lancet.	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.

Summary of Performance Testing

Non-Clinical bench testing was performed per the special controls (878.4850). Cleaning/Disinfecting and Mechanical Robustness verification testing was completed to ensure the safety and usability for the duration of the claimed service life.

Clinical testing is not required for this device. The risk analysis contained in the Risk Management Report confirms that all identified risks were addressed and mitigated appropriately. All residual risks after mitigation were acceptable and communicated in the instructions for use.

Performance testing on the proposed Multi-Lancet Device 2 and ReliOn Premier Lancing Device demonstrate that the devices meet the performance requirements for their intended use.

Proposed Labeling

Labeling adequately communicates to the user the device intended use, safety precautions and directions for use. The labeling meets the requirements documented in the:

1. Regulation for Medical Device Labeling (21 CFR § 801)
2. Regulation for multiple use blood lancet for single patient use only (21 CFR 878.4850 (c)(vi))

Substantial Equivalence Conclusion

The Multi-Lancet Device 2 and ReliOn Premier Lancing Device are substantially equivalent to the predicate Accu-Chek Softclix Lancing Device based on comparisons of the device classifications, intended use, and technological characteristics. Non-clinical performance testing successfully confirmed the suitability of the Multi-Lancet Device 2 and ReliOn Premier Lancing Device for the intended uses and demonstrated the devices are as safe, as effective, and perform as well as the predicate device as required per 21 CFR § 807.92(b)(3).