March 20, 2024

RedDrop Dx
Kris Buchanan
CEO
2401 Research Blvd, #206
Fort Collins, Colorado 80526

Re: K234081
Trade/Device Name: RedDrop ONE (One)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: December 22, 2023
Received: December 22, 2023

Dear Kris Buchanan:

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 and the limitations described below. 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.

The OHT4: Office of Surgical and Infection Control Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling in addition to being placed prominently immediately after any images or references to a collection tube:

1. This device is only for use with compatible collection tubes that are cleared for use with this device;

2. This device is not intended for use as a blood collection kit; and

3. This device is not intended for at-home collection or collection by lay-users.

Furthermore, the indication for use “The RedDrop ONE is a single-use blood lancing device intended for producing microliter capillary whole blood samples. It does not collect or transport such samples.” must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 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,

Binita S. Ashar -S

Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234081

Device Name

RedDrop ONE (One)

Indications for Use *(Describe)*

The RedDrop ONE is a single-use blood lancing device intended for producing microliter capillary whole blood samples. 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:

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"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."

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

Submitter:	RedDrop Dx, Inc. 2401 Research Blvd. #206 Fort Collins, CO 80526 Phone: 970-443-8118 Contact: Kris Buchanan, CEO
Date of Summary:	December 20, 2023
Device Trade Name:	RedDrop ONE Lancet
Common or Usual Name:	Blood Lancet Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation Number:	21 CFR 878.4850
Device Class:	II
Product Code:	FMK
Panel:	General Surgery OHT4
Predicate Device:	TAP Lancet (K223201)
Device Description:	The RedDrop ONE Lancet is a single-use blood lancing device with an integral sharps injury prevention feature intended for producing microliter capillary whole blood samples. The device is adhered to the skin in the selected position on the upper arm. The device is actuated by sliding the actuator causing an energized spring to release and deploy the lancet array. The lancet array is deployed to a maximum depth of 2 mm to access capillaries. The lancet array is then automatically retracted to a safe position that prevents sharps injury and re-activation. Sliding the actuator also releases two spring loaded pistons that create a gentle vacuum to the skin to facilitate the emergence of capillary blood from the sample site.
Intended Use/ Indications for Use:	The RedDrop ONE Lancet is a single-use blood lancing device intended for producing microliter capillary whole blood samples. It does not collect or transport such samples.

Indications for Use Comparison:	The indications for use of the candidate device are the same as the indications for use of the predicate device.
Technological Comparison:	Penetration of capillary blood vessels and application of vacuum to draw out whole blood samples is the underlying principle of both the subject and predicate devices. At a high level, the subject and predicate device are both based on the same technological elements: • A spring-loaded array of sharp needles to penetrate skin to reach capillary vessels. • A retraction mechanism to withdraw the needle array from the skin to a location where it can no longer be accessed. • A lock-out feature to permanently prevent the needles from being re-deployed. • A mechanical means of manual activation. • A means of sealing the device to the skin. • A means of using spring force to create vacuum at the incision site. The following technological differences exist between the subject and predicate devices: • The subject device stores some spring energy in the device that the predicate device requires the user to supply. • The predicate device requires an actuation force that is directed toward the body. A lighter actuation force of the subject device is applied parallel to the body.
Non-Clinical Performance Testing:	Non-Clinical performance testing was conducted to confirm the device met its design specifications, intended use and substantial equivalence. Additional comparison testing to the predicate device was conducted to further support substantial equivalence. Testing also included: Package Integrity Testing including bubble leak per ASTM F2096 and Seal Strength per ASTM F88. Accelerated aging per ASTM F1980. Bacterial Endotoxins testing per ANSI/AAMI ST72.
Clinical Testing, Summary and Conclusions	The usability of the RedDrop ONE device with the instructions for use was evaluated in an actual-use study and is discussed in the clinical testing section of this submission. The device, in conjunction with the instructions for use, was found to be safe

	and effective for the intended use, and all residual risks were deemed acceptable for this type of device. An assessment of clinical performance data for the RedDrop ONE device successfully demonstrated its ability to produce blood samples from the upper arm of human subjects according to the device labeling. Subjects produced their blood samples following the instructions for use. The devices had a total success rate of over 95.0% and demonstrated that they performed as intended. In addition, clinical and useability studies were conducted head-to-head with the predicate device to further confirm substantial equivalence.