10/18/2022

Trividia Health
Jacqueline Davis
Global Regulatory Affairs Specialist IV
2400 N.W. 55th Court
Fort Lauderdale, Florida 33309

Re: K221072
Trade/Device Name: TRUEdraw Lancing Device, Mini Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: September 20, 2022
Received: September 21, 2022

Dear Jacqueline Davis:

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.

Submission Number *(if known)*

K221072

Device Name

TRUEdraw Lancing Device;
Mini Lancing Device

Indications for Use *(Describe)*

The TRUEdraw Lancing Device is for use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the forearm.

The Mini Lancing Device is for use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the forearm.

The TRUEdraw Lancing Device/ Mini Lancing Device is for use only on a single patient in a home setting.

The TRUEdraw Lancing Device/ Mini Lancing Device is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

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.

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K221072 - TRUEdraw Lancing Device; Mini Lancing Device 510(k) Summary

Contact Details	21 CFR 807.92(a)(1)
Applicant Name	Trividia Health
Applicant Address	2400 N.W. 55th Court Ft. Lauderdale, FL 33309 United States
Applicant Contact Telephone	(800) 342-7226
Applicant Contact	Ms. Jacqueline Davis
Applicant Contact Email	jdavis@trividiahealth.com

Device Name	21 CFR 807.92(a)(2)
Device Trade Name	TRUEdraw Lancing Device; Mini Lancing Device
Common Name	Lancing device
Classification Name	Multiple Use Blood Lancet For Single Patient Use Only
Regulation Number	878.4850(c)
Product Code	QRL

Legally Marketed Predicate Device	21 CFR 807.92(a)(3)
Predicate #	K214022
Predicate Trade Name	Accu-Chek Softclix Blood Lancing Device
Product Code	QRL

Device Description Summary 21 CFR 807.92(a)(4)

The TRUEdraw Lancing Device/ Mini Lancing Device is a reusable blood lancet holder intended to be used in conjunction with a sterile, single-use blood lancet for obtaining a capillary blood sample for testing purposes from the fingertip and from alternative sites, such as the forearm. TRUEdraw Lancing Device/ Mini Lancing Device is intended for multiple use by a single patient.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The TRUEdraw Lancing Device is for use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the forearm.

The Mini Lancing Device is for use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the forearm.

The TRUEdraw Lancing Device/ Mini Lancing Device is for use only on a single patient in a home setting.

The TRUEdraw Lancing Device/ Mini Lancing Device is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject devices are the same as the predicate with the exception that the subject devices are indicated for the forearm as an alternative site and the alternative sites for the predicate devices include the palm, upper arm, and forearm.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices have the same technological characteristics as the predicate device in terms of design and general type of materials used, principle of operation, usage, features, and function.

	Subject Devices TRUEdraw Lancing Device; Mini Lancing Device	**Predicate Device** Accu-Chek Softclix Lancing Device (cleared as part of the Accu-Chek Softclix Blood Lancing System under K214022)
Description	The TRUEdraw/ Mini Lancing Device is a reusable lancet base that uses compatible single-use, sterile lancets to obtain a drop of blood from a fingertip or alternative site (forearm) using the clear end 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/ Indications for Use	For use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from the forearm. For use only on a single patient in a home setting. Not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	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. For use only on a single patient in a home setting. Not suitable for use by healthcare professionals with multiple patients in a healthcare setting.
Prescription/over-the-counter use	Over-the-counter	Over-the-counter
Where Device Used	Home	Home
Number of uses	Multiple uses by a single patient	Lancing device: multiple uses by a single patient
Anatomical sites	Fingertip Forearm	Fingertip Ball of the hand (palm) Upper arm Lower arm (forearm)
Principle of operation	Mechanical, spring-driven	Mechanical, spring-driven
Materials	Plastics (body, internal components), metal (internal springs)	Plastics (body, internal components), metal (internal springs)
Depth adjustment	5 levels by twisting nozzle/end cap (finer adjustments can be made by setting the indicator arrow between the numbers)	11 levels by twisting cap
Load and firing	Load lancet by pulling back on the lance body when the lancet is inserted. Fire by pressing the trigger button.	Load lancet by pressing priming button when lancet is inserted. Fire by pressing the release button.
Lancet retracted after use to prevent sharps injury	Yes	Yes

Alternative site cap	Yes	Yes

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)
Nonclinical bench testing was performed per the special controls in 21 CFR 878.4850(c). This included design verification & validation testing to ensure that the lancet blade can be manually changed with every use, that the structure and materials are consistent with the intended use and address the risk of sharp object injuries and blood borne pathogen transmission, and mechanical performance testing to demonstrate that the device will withstand the forces encountered during use.

Description	**Tests Performed**	**Results**
Mechanical performance verification for TRUEdraw lancing device	- Materials and mechanical characteristics - Operation of the lancing device - Product life and shock conditions - Cosmetic attributes	- Pass - Pass - Pass - Pass - Pass
Mechanical performance verification for mini lancing device	- Materials and mechanical characteristics - Operation of the lancing device - Product life and shock conditions - Cosmetic attributes	- Pass - Pass - Pass - Pass - Pass
Compatibility with commonly available general use lancets	- Critical dimensions (lancet body diameter, exposed needle length, body length) - Fit	- Pass - Pass
Cleaning and disinfection validation - TRUEdraw lancing device and alternate site cap	1,095 cleaning and disinfecting cycles using Super Sani-Cloth Wipes.	Pass. The TRUEdraw lancing device and alternate site cap may be cleaned and disinfected with Super Sani-Cloth Wipes once-daily for 3-years.
Cleaning and disinfection validation - mini lancing device and alternate site cap	1,095 cleaning and disinfecting cycles using Super Sani-Cloth Wipes.	Pass. The mini lancing device and alternate site cap may be cleaned and disinfected with Super Sani-Cloth Wipes once-daily for 3-years.

Clinical testing is not applicable.

Conclusion
The results of nonclinical testing demonstrate that the subject devices are as safe, as effective, and perform as well as or better than the predicate device identified above.