November 13, 2023

Roche Diabetes Care, Inc.
Kacia Mills
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, Indiana 46250-0457

Re: K232488
Trade/Device Name: Accu-Chek Safe-T-Pro Plus Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 17, 2023
Received: August 17, 2023

Dear Kacia Mills:

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. 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.

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.11.13 14:48:49 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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.

510(k) Number *(if known)*
K232488

Device Name
Accu-Chek Safe-T-Pro Plus Lancing Device

Indications for Use *(Describe)*
The Accu-Chek Safe-T-Pro Plus lancing device is intended to produce a capillary blood sample for testing utilizing small amounts of blood.

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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K232488 - Accu-Chek Safe-T-Pro Plus Lancing Device 510(k) Summary

Contact Details [21 CFR 807.92(a)(1)]

Applicant Name: Roche Diabetes Care, Inc.
Applicant Address: 9115 Hague Road Indianapolis, IN 46250-0457; United States of America
Applicant Contact Telephone: +1 317-709-4223
Applicant Contact: Mrs. Kacia Mills
Applicant Contact Email: kasey.mills@roche.com

Device Name [21 CFR 807.92(a)(2)]

Device Trade Name: Accu-Chek Safe-T-Pro Plus Lancing Device
Common Name: Blood Lancets
Classification Names: Single use only blood lancet with an integral sharps injury prevention feature
Regulation Number: 878.4850, Class II
Product Code: FMK

Legally Marketed Predicate Devices [21 CFR 807.92(a)(3)]

Predicate #1: K220849
Predicate Trade Name: Accu-Chek Safe-T-Pro Plus Lancing Device
Product Code: FMK

Legally Marketed Reference Devices [21 CFR 807.92(a)(3)]

Reference #1: K222090
Predicate Trade Name: Safety Lancet
Product Code: FMK
Reference #2: K221433
Predicate Trade Name: Facet 28G Universal Lancet
Product Codes: QRK, QRL

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

The Accu-Chek Safe-T-Pro Plus lancing device is a sterile, single-use, disposable lancing device intended to be used by non-professional users 18 years and older and healthcare professionals. It is designed for capillary blood sampling from the fingertip of adults and children 1 year and older or, if the patient is a child under 1 year, from the heel.

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

The Accu-Chek Safe-T-Pro Plus lancing device is intended to produce a capillary blood sample for testing utilizing small amounts of blood.

Similarities / Differences Between Candidate, Predicate, and Reference Devices

	Predicate Device – Accu-Chek Safe-T-Pro Plus Lancing Device	**Candidate Device - Accu-Chek Safe-T-Pro Plus Lancing Device**	**Reference Device 1 – Safety Lancet (K222090)**	**Reference Device 2 – Facet 28G Universal Lancet (K221433)**
Device description	The Accu-Chek Safe-T-Pro Plus lancing device is a needle used for capillary blood sampling for use in diagnostic testing. The Accu-Chek Safe-T-Pro Plus lancing device contains a sharps injury prevention feature where the lancet is retracted and concealed before and after use. Once the lancet is used, it is rendered inoperative. The device is designed for single use only.	The Accu-Chek Safe-T-Pro Plus lancing device is a needle used for capillary blood sampling for use in diagnostic testing. The Accu-Chek Safe-T-Pro Plus lancing device contains a sharps injury prevention feature where the lancet is retracted and concealed before and after use. Once the lancet is used, it is rendered inoperative. The device is designed for single use only.	Safety Lancet, could be divided into Model XY, Model XH, and Model XA according to the design features and key functional elements. The device is sterilized by Gamma ray (Co-60 or e-beam) and for single use. The shelf life is 5 years.	The Facet 28G Universal Lancet (Facet Lancet) is a sterile, single use, blood sampling device used to obtain a sample of capillary blood for diagnostic purposes, primarily for blood glucose monitoring in diabetic patients.
Indications for Use	The Accu-Chek Safe-T-Pro Plus lancing device is a sterile, single-use, disposable lancing device intended to be used by healthcare professionals. It is designed for capillary blood sampling from the fingertip of adults and children 1 year and older or, if the patient is a child under 1 year, from the heel.	The Accu-Chek Safe-T-Pro Plus lancing device is intended to produce a capillary blood sample for testing utilizing small amounts of blood.	Safety Lancet is intended to be used to obtain capillary blood sample to perform medical testing, including blood glucose monitoring and for tests using small amounts of blood.	The Facet 28G Universal Lancet is a sterile, disposable single use device used to obtain a droplet of capillary blood for subsequent diagnostic testing from the finger or an alternative site, such as the palm, upper arm, or forearm. The Lancet is to be properly disposed of after a single use on an individual child, adolescent, or adult patient in home testing.
Intended Users	Healthcare professionals	Healthcare professionals and consumers	Consumers	Consumers

K232488 - Accu-Chek Safe-T-Pro Plus Lancing Device 510(k) Summary

	Predicate Device – Accu-Chek Safe-T-Pro Plus Lancing Device	**Candidate Device - Accu-Chek Safe-T-Pro Plus Lancing Device**	**Reference Device 1 – Safety Lancet (K222090)**	**Reference Device 2 – Facet 28G Universal Lancet (K221433)**
Number of Uses	Single use only with integral sharps injury prevention feature	Same	Same	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature and Multiple Use Blood Lancet For Single Patient Use Only
Device images				Not available
Lancet Sterility	Gamma irradiation	Same	Same	Same

	Predicate Device – Accu-Chek Safe-T-Pro Plus Lancing Device	**Candidate Device - Accu-Chek Safe-T-Pro Plus Lancing Device**	**Reference Device 1 – Safety Lancet (K222090)**	**Reference Device 2 – Facet 28G Universal Lancet (K221433)**
Needle Gauge and Depth levels	23 Gauge needle with 3 depth levels by twisting cap: 1.3 mm 1.8 mm 2.3 mm	Same	Model XY • Dimension/gauge: 21G,23G,25G,26G, 28G,30G (Needle type),1.2mm (Blade type) • Penetration depth: 1.4mm-2.8mm(Needle type), 1.6mm-2.0mm (Blade type) Model XH • Dimension/gauge: 18G,21G,23G,28G (Needle type), 1.5mm (Blade type) • Penetration depth: 1.2mm-2.8mm (Needle type), 1.6mm-2.0mm(Blade type) Model XA • Dimension/gauge: 21G,23G,28G (Needle type) • Penetration depth: 1.3mm/1.8mm/2.3mm, 1.5mm/2.0mm/2. 5mm (Needle type)	28 Gauge needle, multiple depth options depending on multiple use blood lancet device used with single use only blood lancet
Mechanical loading	Spring-driven	Same	Same	Same for multiple use blood lancet device in which the single use blood lancet is used

	Predicate Device – Accu-Chek Safe-T-Pro Plus Lancing Device	**Candidate Device - Accu-Chek Safe-T-Pro Plus Lancing Device**	**Reference Device 1 – Safety Lancet (K222090)**	**Reference Device 2 – Facet 28G Universal Lancet (K221433)**
Load and firing	Loading / priming the device is not required. Press release button to activate lancet mechanism.	Same	Same	Loading is required.
Anatomical sites	Fingertip (adults and children 1 year and older) Heel (child under 1 year)	Same	Fingertip	Fingertip, palm, upper arm, forearm
Sharps injury prevention	The Accu-Chek Safe-T-Pro Plus lancing device is designed with a sharps injury prevention feature. It is a passive safety mechanism that automatically activates after the device is used, requiring no action on the part of the user. The lancet remains in the housing before and after use. After activation, the single-use device cannot be used again.	Same	Same	N/A

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

The indications for use statement of the candidate device and of the predicate device are not identical. However, the intended use is the same, which is to obtain a blood sample for diagnostic testing. The package insert for the candidate device was updated to clearly separate indications for use and the intended test population.

Technological Comparison [21 CFR 807.92(a)(6)]

The technological characteristics of the candidate device are the same as the predicate.

Non-Clinical Testing Summary and Conclusions [21 CFR 807.92(b)]

Nonclinical bench testing was performed per the applicable FDA Guidance documents (Sharps Injury Prevention Features) and special controls (878.4850). This includes (mechanical) design verification and validation testing in order to ensure the risks were appropriately managed, in addition to verifying that the device's mechanical functions are suitable for use over the lifetime of the device. See more in attached Verification Summary.

Clinical Testing is not applicable; risk analysis confirmed that all identified risks were addressed and mitigated appropriately. All residual risks after mitigation were acceptable, and communicated in the instructions for use as warnings. There were no special performance or safety concerns identified. See Risk documents provided in Biocompatibility section.

The Accu-Chek Safe-T-Pro Plus Lancing device is safe and effective for its intended use, and performs as well or better than the legally marketed predicate device and legally marketed reference devices.