May 19, 2022

Roche Diabetes Care, Inc.
Jason Lee
Senior Quality Lead
9115 Hague Road
Indianapolis, Indiana 46256

Re: K220849
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: March 22, 2022
Received: March 23, 2022

Dear Jason Lee:

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,

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)*

K220849

Device Name

Accu-Chek Safe-T-Pro Plus Lancing Device

Indications for Use *(Describe)*

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.

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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*"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."*

# 510(k) Summary

Prepared on: 2022-03-22

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Roche Diabetes Care, Inc. |
| Applicant Address | 9115 Hague Road Indianapolis IN 46256 United States |
| Applicant Contact Telephone | 1-317-435-4782 |
| Applicant Contact | Mr. Jason Lee |
| Applicant Contact Email | jason.lee.jl1@roche.com |
| Correspondent Name | Roche Diabetes Care, Inc. |
| Correspondent Address | 9115 Hague Road Indianapolis IN 46256 United States |
| Correspondent Contact Telephone | 1-317-840-9231 |
| Correspondent Contact | Mrs. Ginger Emrich |
| Correspondent Contact Email | ginger.emrich@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 Name | Blood lancets |
| Regulation Number | 878.4850 |
| Product Code | FMK |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| k101145 | SurgiLance Safety Lancets | FMK |

## 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 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 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.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the candidate device are the same as the predicate.

## Technological Comparison 21 CFR 807.92(a)(6)

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

## Non-Clinical and/or Clinical Tests Summary & 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 & validation testing in order to 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 Biocompatability 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.