April 5, 2022

Roche Diabetes Care, Inc.
Julia Best
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, Illinois 46055

Re: K220364
Trade/Device Name: Accu-Chek Safe-T-Pro Uno Lancing Device
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class II
Product Code: FMK
Dated: February 3, 2022
Received: February 8, 2022

Dear Julia Best:

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)*

K220364

Device Name

Accu-Chek Safe-T-Pro Uno Lancing Device

Indications for Use *(Describe)*

The Accu-Chek Safe-T-Pro Uno 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.

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K220364 - Accu-Chek Safe-T-Pro Uno 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: +49 173 3198175
Applicant Contact: Mrs. Julia Best
Applicant Contact Email: julia.best@roche.com

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

Device Trade Name: Accu-Chek Safe-T-Pro Uno 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 #: K101145
Predicate Trade Name: SurgiLance Safety Lancets
Product Code: FMK

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

The Accu-Chek Safe-T-Pro Uno 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 Uno 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.

K220364 - Accu-Chek Safe-T-Pro Uno Lancing Device 510(k) Summary

Similarities / Differences from Candidate Device to Predicate Device

	Predicate Device - SurgiLance K101145	**Candidate Device - Accu-Chek Safe-T-Pro Uno Lancing Device K220364**
Device description	The SurgiLance Safety Lancet is a needle or blade device used to prick a test site to draw a micro-sample of blood which can then be tested for an array of diagnostic assays. The SurgiLance Safety Lancet is safely retracted and concealed before and after use. Once the lancet is used, it is rendered inoperative, providing added safety for patient and clinician. The device is discarded after use.	The Accu-Chek Safe-T-Pro Uno lancing device is a needle used for capillary blood sampling for use in diagnostic testing. The Accu-Chek Safe-T-Pro Uno 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.
Intended use	The SurgiLance Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury.	The Accu-Chek Safe-T-Pro Uno 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 Users	Healthcare professionals and consumers	Healthcare professionals only
Number of Uses	Single use only with integral sharps injury prevention feature	Same

K220364 - Accu-Chek Safe-T-Pro Uno Lancing Device 510(k) Summary

	Predicate Device - SurgiLance K101145	**Candidate Device - Accu-Chek Safe-T-Pro Uno Lancing Device K220364**
Device images	 	
Lancet Sterility	Yes, gamma irradiation	Same
Needle Gauge and Depth levels	Six models for different depth settings, differentiated by casing color: Yellow: 21 Gauge – 1.0 mm depth Gray: 21 Gauge – 1.8 mm depth Orange: 21 Gauge – 2.2 mm depth Pink: 21 Gauge – 2.8 mm depth Lime: 18 Gauge – 1.8 mm depth Blue: 18 Gauge – 2.3 mm depth	Only one model: 28 Gauge needle – 1.5 mm depth
Mechanical loading	Spring-driven	Same

K220364 - Accu-Chek Safe-T-Pro Uno Lancing Device 510(k) Summary

	Predicate Device - SurgiLance K101145	**Candidate Device - Accu-Chek Safe-T-Pro Uno Lancing Device K220364**
Load and firing	Loading / priming the device is not required. Press red end of lancet down against test site to activate lancet mechanism.	Loading / priming the device is not required. Press release button to activate lancet mechanism.
Anatomical sites	• Test site • Fingertip	• Fingertip (adults and children 1 year and older) • Heel (child under 1 year)
Sharps injury prevention	The SurgiLance Safety Lancet has a passive safety mechanism that automatically activates after use requiring no action by the user. The lancet is safely retracted and concealed before and after use. Once the lancet is used, it is rendered inoperative.	Same

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 & 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.

Conclusions

The predicate and the candidate device are both used to obtain a blood sample for diagnostic testing. Furthermore, both are sterile, single-use lancets with a sharps injury prevention feature, following the same mechanical load mechanism. In conclusion, the Accu-Chek Safe-T-Pro Uno Lancing Device is substantially equivalent to the SurgiLance Safety Lancets. The Accu-Chek Safe-T-Pro Uno Lancing device is safe and effective for its intended use, and performs as well or better than the legally marketed predicate device.