February 17, 2022

Roche Diabetes Care, Inc.
Mr. Cameron Smith
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, Indiana 46250

Re: K214022
Trade/Device Name: Accu-Chek Softclix Blood Lancing System
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK

Dated: December 21, 2021
Received: December 22, 2021

Dear Mr. Cameron Smith:

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.

510(k) Number *(if known)*
K214022

Device Name
Accu-Chek Softclix Blood Lancing System

Indications for Use *(Describe)*
The Accu-Chek Softclix Blood Lancing System is intended 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.

The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.

This system is for use only on a single patient in a home setting.

This system 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.

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K214022 - Accu-Chek Softclix Blood Lancing System 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: (317) 696-1965
Applicant Contact: Mr. Cameron Smith
Applicant Contact Email: cameron.smith.cs1@roche.com

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

Device Trade Name: Accu-Chek Softclix Blood Lancing System
Common Name: Blood Lancets
Classification Names: Blood Lancets
Regulation Number: 878.4850, Class II
Product Code: QRL, QRK

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

Predicate #: K810075
Predicate Trade Name: Autoclix Lancet
Product Code: FMK

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

The Accu-Chek Softclix Lancing Device uses compatible Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternative sites. The Accu-Chek Softclix Blood Lancing System consists of three components:

1. Accu-Chek Softclix Lancing Device
2. Accu-Chek Softclix Lancets
3. Accu-Chek Softclix Alternative Site Testing (AST) Cap

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

The Accu-Chek Softclix Blood Lancing System is intended 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. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.
This system is for use only on a single patient in a home setting.
This system 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 candidate device are the same as the predicate with the exception that the predicate device has people with diabetes as clients, and the candidate device is for general use.

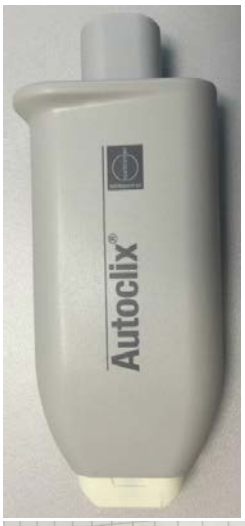
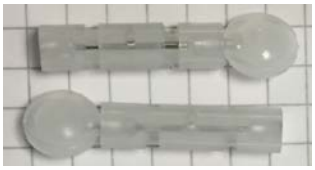
Technological Comparison [21 CFR 807.92(a)(6)]

The candidate and predicate devices share the same technological characteristics including their design, mechanical mechanism, principle of operation, energy source and usage, features, form, fit, and function.

Similarities / Differences from Candidate Device to Predicate Device

	Predicate Device – Autoclix K810075	**Candidate Device** – Accu-Chek Softclix Blood Lancing System K214022
Device description	Autoclix is an automatic device used to obtain a drop of blood from the fingertip, ear lobe or heel. It operates in conjunction with the Autoclix Lancet, a sterile, disposable blood lancet.	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	The Autoclix Lancet is intended for the painless, safe and hygienic collection of capillary blood, preferably from the side of the finger tip for diagnostic purposes.	The Accu-Chek Softclix Blood Lancing System is intended 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.
Indications for use	● The Autoclix Lancet, as an aid for patients to prick themselves in order to perform self-controls, shall only be used by a single patient. It is not suitable for professional ("multi-user") application. ● People with diabetes are considered as clients, although the use of the product in the neonatal field is not admissible.	● The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. ● This system is for use only on a single patient in a home setting. ● This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.
Number of Uses	● Base (lancing device): multiple use ● Lancet: single use	● Base (lancing device): multiple use ● Lancet: single use

K214022 - Accu-Chek Softclix Blood Lancing System 510(k) Summary

	Predicate Device – Autoclix K810075	**Candidate Device** – Accu-Chek Softclix Blood Lancing System K214022
Device images	Lancing Device (and pressure platforms):   Lancet: 	Lancing Device (and AST Cap):  Lancet: 
Lancet Sterility	Yes, gamma irradiation	Yes, gamma irradiation
Needle	0.4mm (28G); 3-facet cut	0.4mm (28G); beveled cut with 3 facets
Depth adjustment	3 levels by using different pressure platforms	11 levels by twisting cap
Mechanical loading	Spring-driven	Spring-driven
Load and firing	• Load with pressing the plunger when lancet is inserted, • Fire with pressing the pressure platform.	• Load by pressing priming button when lancet is inserted, • Fire by pressing the release button.
Anatomical sites	• Fingertip • Ear lobe • Heel	• Fingertip • Ball of the hand (palm) • Upper arm • Lower arm (forearm)

	Predicate Device – Autoclix K810075	**Candidate Device** – Accu-Chek Softclix Blood Lancing System K214022
Sharps injury prevention	The Autoclix is designed so that it can be reset to operate only after the used lancet has been ejected. In this way, multiple punctures with a used lancet are prevented. Automatic ejection of used lancets is done by pressing the plunger.	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.

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.

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.

Conclusions

The results of nonclinical testing demonstrate that the candidate device has a substantially equivalent safety and effectiveness profile to the predicate device and should perform as intended in the specified use conditions as well as the predicate device per required standards.