August 10, 2023

Roche Diabetes Care, Inc.
Wolfgang Handel
Regulatory Affairs Project Lead
9115 Hague Road
Indianapolis, IN 46250-0457

Re: K213134
Trade/Device Name: Accu-Chek Solo micropump system with interoperable technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: February 10, 2023
Received: February 10, 2023

Dear Wolfgang Handel:

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 and Part 809); 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
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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)*
K213134

Device Name
Accu-Chek Solo micropump system with interoperable technology

Indications for Use *(Describe)*
The Accu-Chek Solo micropump system with interoperable technology is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Accu-Chek Solo micropump system is able to communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Accu-Chek Solo micropump system is intended for single patient, home use and requires a prescription. The Accu-Chek Solo micropump system is indicated for use in individuals 2 years of age and greater.

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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K213134 – Accu-Chek Solo micropump system with interoperable technology 510(k) Summary

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

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

Device Trade Name: Accu-Chek Solo micropump system with interoperable technology
Common Name: Infusion pump
Classification Names: Alternate Controller Enabled Insulin Infusion Pump
Regulation Number: 880.5725
Class II Product Code: QFG

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

Predicate #: K191679
Predicate Trade Name: Omnipod DASH Insulin Management System with Interoperable Technology
Product Code: QFG

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

The Accu-Chek Solo micropump is a portable programmable insulin pump, which adheres to the patient's skin. The patch is comprised of two connected parts: a disposable reservoir, in which the insulin is stored and a reusable pump, which includes the pumping mechanism and electronic components. The patch is controlled via a connected Device. The Accu-Chek Solo micropump is designed to deliver basal and bolus insulin doses at various rates, volumes and patterns, as prescribed by the user's physician.

Technology Description

The Accu-Chek Solo micropump System Patch Pump's technological characteristics are the same as those of its predicate devices. Same as its predicates, Accu-Chek Solo micropump is an external, portable insulin infusion pump controlled by a connected Device. Same as predicate device Accu-Chek Solo micropump System communication is by means of radio frequency. Same as predicate devices, Accu-Chek Solo micropump System insulin dispensing patch is worn on the user's skin.

Accu-Chek Solo micropump includes the same functions as the predicate devices.

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

Prescription Use (Part 21 CFR 801 Subpart D)

The Accu-Chek Solo micropump system with interoperable technology is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Accu-Chek Solo micropump system is able to communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Accu-Chek Solo micropump system is intended for single patient, home use and requires a prescription. The Accu-Chek Solo micropump system is indicated for use in individuals 2 years of age and greater.

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

The Accu-Chek Solo Micropump described in this submission is substantially equivalent to the predicate device.

The Accu-Chek Solo Micropump System uses the same indications for use.

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

The Accu-Chek Solo micropump System uses the same technology and modes of operation as the predicate device.

The Accu-Chek Solo micropump System is a device that is substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness. The Performance testing of the Accu-Chek Solo micropump System demonstrated that the device met all device specifications. Therefore, the device is substantially equivalent to the predicate device.

Similarities / Differences from Candidate Device to Predicate Device

	Accu-Chek Solo micropump system with interoperable technology	Omnipod DASH Insulin Management System With Interoperable Technology
Manufacturer	Roche Diabetes Care Inc.	Insulet Corporation
K number	K213134	K191679
Code	QFG	QFG
Indications for use	The Accu-Chek Solo micropump system with interoperable technology is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Accu-Chek Solo micropump system is able to communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Accu-Chek Solo micropump system is intended for single patient, home use and requires a prescription. The Accu-Chek Solo micropump system is indicated for use in individuals 2 years of age and greater.	The Omnipod DASH Insulin Management System (the Pump) with interoperable technology is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog, Humalog, Admelog, or Apidra U-100 insulin.
Contraindications	The micropump system should not be used by children under 2 years of age or by people who regularly require less than 0.1 U/h of basal insulin or by people who have an insulin sensitivity above 1.00 U : 200 mg/dL. It is the responsibility of the healthcare professional to decide whether the accuracy of the delivery rate is adequate for the patient in question. Continuous Subcutaneous Insulin Infusion (CSII) with the micropump system is not recommended or only recommended with limitations for the following groups of people: ● People who are not able or willing to either perform at least 4 blood glucose tests per day or use a continuous glucose monitoring (CGM) system reliably. ● People who are not able to be in regular contact with their healthcare professional. ● People who do not understand what is required for insulin pump therapy or who are not able to follow the instructions for use of the micropump system. ● People who cannot be relied upon due to drug addiction, substance abuse or mental illness.	Insulin pump therapy is not intended for anyone unable or unwilling to ● Unable to perform at least four (4) blood glucose tests per day ● Unable to maintain contact with their healthcare provider ● Unable to use the Omnipod DASH™ System according to instructions

	Accu-Chek Solo micropump system with interoperable technology	Omnipod DASH Insulin Management System With Interoperable Technology
	● People who are exposed to high ambient temperatures on a regular basis ● People with skin that does not tolerate adhesive pads. ● People who often experience a cannula occlusion. ● People who are not able to notice either visual, accoustic or vibration alarms. This includes people with a combination of hearing loss, neuropathy, vision impairment or other concomitant physical limitations.	
Pump design	Single use Reservoir, cannula and pump holder and resusable pump	Single-use on-body pump with wireless controller
Skin contact /	Pump holder with adhesive and Cannula	Pod with adhesive and Cannula
Administration sets	Soft cannula Insertion depth: 6 and 9 mm	Soft cannula Insertion depth: 6-7 mm
Reservoir/ cartridge lifetime	Up to 96 hours (or less, depend on the insulin type) restricted by drug labeling	Up to 72 hours
Reservoir / cartridge volume (deliverable)	200 units	200 units
Communication	Bluetooth low energy	Bluetooth low energy
Insulin Type and Brands	U100 Insulin ● Humalog ● Novolog ● Apidra ● Fiasp	U100 Insulin ● Humalog ● NovoLog ● Apidra ● Fiasp (K) ● Admelog
Min. basal rate	0.10 U/hr	0.05 U/hr
Max. basal rate	25 U/hr	30 U/hr
Min. bolus	0.2 Units	0.05
Max. bolus	35 Units	30 Units
Button press bolus	Yes (on pump)	Yes (on PDM)
Accuracy of Insulin Delivery Basal rate (tested per IEC 60601-2-24))	±18% or better at 0.1 U/h ±5% or better at 1.0 U/h	± 5% at rates ≥ 0.05 U/hr
Accuracy of Insulin Delivery Bolus (tested per IEC 60601-2-24 & FDA special controls)	±30 % or better at 0.2 U up to < 1.0 U ±5% or better for 1.0 U up to 35.0 U	±5%
Occlusion	1 IU/h 3h 29 min 0.1 IU/h 26h 53 min	1 IU/h 3 h 0.05 IU/h 51 h

	Accu-Chek Solo micropump system with interoperable technology		Omnipod DASH Insulin Management System With Interoperable Technology	
detection time Basal delivery---average time to occlusion detection				
Occlusion detection time Basal delivery---Maximum time to occlusion detection	1 IU/h 0.1 IU/h	7h 45 min 71h	1 IU/h 0.05 IU/h	5.5 h 80 h
Occlusion detection time Bolus average time to occlusion detection	25 IU	1 min 11 sec	5 IU	33 min
Occlusion detection time Bolus maximum time to occlusion detection	25 IU	5 min 16 sec	5 IU	35 min

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

Design verification and validation testing was performed to ensure the Accu-Chek Guide Solo diabetes manager Blood Glucose monitoring system met design specifications and requirements. Testing is summarized below:

Human Factors

Validation of the device system was performed in accordance with FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016 and IEC 62366-1, in which safety critical tasks were identified, safeguards identified and implemented, then tested for their residual risk. The System validation demonstrated that the device is validated for its intended use.

Biocompatibility

Verification testing completed in accordance with ISO 10993 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" dated September 4, 2020

– Part 1: Evaluation and Testing Within a Risk Management Process
– Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
– Part 5: Tests for in vitro cytotoxicity
– Part 6: Tests for local effects after implantation
– Part 7: Ethylene Oxide Sterilization Residuals
– Part 10: Tests for irritation and skin sensitization
– Part 11: Tests for systemic toxicity
– Part 17: Establishment of allowable limits for leachable substances
– Part 18: Chemical Characterizations of Materials.

Sterility

The sterile parts are sterilized with Ethylenoxid. For the process the ISO 11135 was considered. The tests for the sterile barrier include the requirements of ISO 11607

Insulin Compatibility and Stability

The insulin compatibility was tested with NovoLog, Apidra, Fiasp and Humalog U-100 insulin. Therefore in vitro tests were performed which shows that the tested insulins are compatible with the Accu-Chek Solo micropump.

Safety, Electrical Safety, Essential Performance and Electromagnetic Compatibility (EMC)

Safety, Electrical Safety, and EMC testing were conducted in accordance with

– IEC 60601-1 for Basic Safety and Essential Performance

– IEC 60601-1-2 for Electromagnetic Disturbances

– IEC 60601-1-6 for Usability

– IEC 60601-1-8 for Alarms

– IEC 60601-1-11 for Systems Used in the Home Healthcare Environment.

Software

Software verification and validation testing was conducted and documentation provided in accordance with

– IEC 62304

– FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005

Cybersecurity

Cybersecurity Analysis and testing was conducted and documented in accordance with

– FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" dated October 2, 2014.

Interoperability

An approach was shared on how to deal with potential interoperable devices. This include how the companies work together, who is responsible for what (testing, complaints, reporting, data exchange,…)

The content considered the Guidance document "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices" (September 6, 2017)

Testing: In addition to the performance testing described above, mechanical testing, simulated use testing, and other device verification testing was conducted to demonstrate that the system meets its intended use and is safe, reliable, and all safety and reliability critical requirements have been adequately verified.

Testing to Support System Reliability

- Electrical Specification Testing
- Wire Drive Testing
- RF Throughput Test Report
- Design Visual Inspection

Testing to Support System Safety

- Environmental Safety Testing to 60601-1-11
- Safety and Essential Performance Testing to 60601-1
- Pump Activation and Deactivation Testing
- Pump/Controller Connectivity Testing
- Insulin Delivery Verification Testing

Clinical tests of the insertion process

The aim of the clinical study was to prove that the insertion process for the Accu-Chek Solo Cannula is safe, robust, and virtually pain-free when the cannula is inserted into the subcutaneous fat tissue by the intended user.

Conclusions

The results of bench performance and clinical performance testing demonstrate that the candidate device is substantially equivalent to the predicate device, Omnipod DASH Insulin Management System With Interoperable Technology (k191679).

The results of nonclinical and clinical performance 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.