510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K213134

B Applicant

Roche Diabetes Care GmbH

C Proprietary and Established Names

Accu-Chek Solo micropump system with interoperable technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	Class II	21 CFR 880.5730 - Alternate Controller Enabled Pump	CH - Clinical Chemistry

E Purpose for Submission:

New device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

This device is for prescription use only.

This device should not be used by people who have an insulin sensitivity above 200 mg/dL/U.

It is the responsibility of the healthcare professional to decide whether the accuracy of the delivery rate is adequate for the patient in question.

The Accu-Chek Solo micropump system with interoperable technology is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels at least 4 times per day or use a continuous glucose monitoring system reliably.
- Understand or follow the instructions for use of the micropump system.
- See their healthcare team regularly.

The user must not:

- Be exposed to high ambient temperatures on a regular basis.
- Have difficulty tolerating adhesive pads.
- Experience cannula occlusion often.
- Have impairments that would make it hard to notice visual, acoustic or vibration alarms.

Do not use the micropump system close to strong electromagnetic fields or ionizing radiation like X-rays, Magnetic Resonance Imaging (MRI) and computed tomography (CT). Stop the micropump and remove it from your body before you enter areas with electromagnetic or ionizing radiation.

The device is designed to use rapid-acting U-100 insulin. The Accu-Chek Solo micropump system with interoperable technology is compatible with the following U-100 insulins: Novolog, Apidra, Fiasp, and Humalog. Novolog, Fiasp and Humalog are compatible with the system for use up to 96 hours (4 days), and Apidra is compatible with the system for up to 48 hours (2 days).

III Device Description

The Accu-Chek Solo micropump system with interoperable technology is a portable programmable insulin micropump, which adheres to the patient's skin. The patch comprises a disposable reservoir, in which the insulin is stored, a reusable pump, which includes the pumping mechanism and electronic components, sterile consumables that include the reservoir assembly, a cannula assembly that comes in two cannula lengths of 6 mm and 9 mm and the pump holder which is an adhesive pad that adheres to the skin and fixes the cannula and the micropump in place. The micropump system also comes with a reusable insertion device which is used to attach the infusion assembly into the subcutaneous tissue. The recommended infusion sites include the abdominal region, upper arm, thigh, hip, lower back, and the buttocks.

The pump is controlled via a connected Accu-Chek Guide Solo diabetes manager. The Accu-Chek Solo micropump system with interoperable technology is designed to deliver basal and bolus insulin doses at various rates, volumes, and patterns, as prescribed by the user's physician.

The micropump includes two "Quick Bolus Buttons" which allow for programming and delivering insulin directly by the insulin pump. To avoid an accidental or unintended triggering of an action, the buttons are placed at the opposite side panels of the micropump and need to be pressed simultaneously with two fingers. The micropump exclusively uses audible signals for pump specific notifications.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Omnipod DASH Insulin Management System with Interoperable Technology

B Predicate 510(k) Number(s):

K191679

C Comparison with Predicate(s):

Device & Predicate Device(s):	K213134	K191679
Device Trade Name	Accu-Chek Solo micropump system with interoperable technology	Omnipod DASH Insulin Management System with Interoperable Technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin at variable rates for the management of diabetes mellitus in people requiring insulin. Intended to be interoperable with connected devices including CGMs and automated insulin dosing algorithms.	Same
Operating Environment	Home Use	Same

Insulin Delivery Modes	Both basal and bolus	Same
General Device Characteristic Differences		
Specific Drug/Biologic Use	U-100 Insulin. System has been tested with Novolog, Humalog, Apidra, and Fiasp.	U-100 Insulin. System has been tested with Novolog, Humalog, Admelog and Apidra.
Insulin Basal Rate Delivery Range	0.1 – 25 U/hour	0.05 – 30 U/hour
Insulin Bolus Delivery Range	Programmable from 0.2 - 35 U. Increments depend on the bolus amount.	Programmable from 0.05 - 30 U in 0.05 U increments.

V Standards/Guidance Documents Referenced:

- FDA Guidance "Infusion Pumps Total Product Life Cycle" dated December 2, 2014
- FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" dated February 3, 2016
- FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005
- FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" dated October 2, 2014
- FDA Guidance "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices" dated September 6, 2017
- ISO 10993-1:2009 Biological Evaluation of Medical Devices: Evaluation and Testing
- ISO 10993-3:2014 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ISO 10993-17:2006 Biological Evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials

- ISO 14971 Second Edition 2007-03-01 Medical Devices – Application of Risk Management to Medical Devices
- IEC 60601-1-1 Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances-Requirements and Tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-8 Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
- IEC 60601-1-11 Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard- Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- IEC 62366-1:2015 Medical Devices – Part 1: Application Of Usability Engineering To Medical Devices
- ISO 11607-1:2017 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

VI Performance Characteristics:

A. Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy at 0.1 and 1.0 U/h, 24 aged micropumps and disposables (reservoir, cannula and pump holder assemblies) were tested. For 25 U/h, both aged and unaged pumps and disposables were equally pooled resulting in data from a total of 36 micropumps. Delivery accuracy was assessed by pumping insulin into a container on a scale and measuring the weight of the liquid at 1h, 6h, and 12h intervals for minimum and intermediate rates (0.1 and 1.0 U/hr) and 1h and 6h intervals for maximum rate (25 U/hr).

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for minimum, intermediate, and maximum basal rate settings for all pumps tested.

Table 1: Amount of fluid delivered after 1, 6, and 12 hours with 0.1 U/hr (minimum) basal rate setting

0.1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**0.1 U**	**0.6 U**	**1.2 U**
Median amount delivered [min, max]	0.08 U [0.04, 0.36]	0.54 U [0.33, 0.67]	1.08 U [0.69, 1.29]

Table 2: Amount of fluid delivered after 1, 6, and 12 hours with 1 U/hr (intermediate) basal rate setting

1 U/hr Basal Duration	**1 hour**	**6 hours**	**12 hours**
Total expected delivery volume	**1.0 U**	**6.0 U**	**12.0 U**
Median amount delivered [min, max]	1.00 U [0.54, 1.08]	5.93 U [5.26, 6.10]	11.86 U [11.18, 12.11]

Table 3: Amount of fluid delivered after 1, 6, and 12 hours with 25 U/hr (high) basal rate setting

25 U/hr Basal Duration	**1 hour**	**6 hours**
Total expected delivery volume	**25 U**	**150 U**
Median amount delivered [min, max]	25.15 U [24.96, 25.31]	149.19 U [148.69, 149.81]

2. Bolus delivery accuracy

To assess bolus delivery accuracy, 36 pumps were tested by delivering at minimum, intermediate, and maximum bolus volumes (0.2 U, 1.0 U, 6.0, and 35 U). All four combinations of aged and unaged pump and disposables were tested in equal distribution. Each combination included 9 unique pumps which were used to test all 4 bolus amounts.

Tables 4-6 below show the number (and %) of boluses within the specified range of the minimum bolus, one intermediate bolus and the maximum bolus volume.

Table 4: Amount of fluid delivered after a 0.2 U bolus request (n=1619 boluses)

Units delivered after a 0.2 U bolus request (% of commanded units)										
	<0.05 (<25%)	0.05 -0.15 (25-75%)	0.15-0.18 (75-90%)	0.18-0.19 (90-95%)	0.19-0.21 (95-105%)	0.21-0.22 (105-110%)	0.22-0.25 (110-125%)	0.25-0.35 (125-175%)	0.35-0.5 (175-250%)	>0.5 (>250%)
Number and percent of boluses	0/1619 (0.0 %)	89/1619 (5.5 %)	266/1619 (16.43 %)	333/1619 (20.57 %)	717/1619 (44.29 %)	104/1619 (6.42 %)	83/1619 (5.13 %)	27/1619 (1.67 %)	0/1619 (0 %)	0/1619 (0 %)

Table 5: Amount of fluid delivered after a 6.0 U bolus request (n=216 boluses)

Units delivered after a 6.0 U bolus request (% of commanded units)										
	<1.50 (<25%)	1.50-4.50 (25-75%)	4.5-5.40 (75-90%)	5.40-5.70 (90-95%)	5.70-6.30 (95-105%)	6.30-6.60 (105-110%)	6.60-7.5 (110-125%)	7.5-10.5 (125-175%)	8.75-15.0 (175-250%)	>15.0 (>250%)
Number and percent of boluses	0/216 (0.0%)	0/216 (0.0%)	0/216 (0.0%)	1/216 (0.46%)	215/216 (99.54%)	0/216 (0.0%)	0/216 (0.0%)	0/216 (0.0%)	0/216 (0.0%)	0/216 (0.0%)

Table 6: Amount of fluid delivered after a 35 U bolus request (n=108 boluses)

Units delivered after a 35.0 U bolus request (% of commanded units)										
	<8.75 (<25%)	8.75-26.25 (25-75%)	26.25-31.5 (75-90%)	31.50-33.25 (90-95%)	33.25-36.75 (95-105%)	36.75-38.5 (105-110%)	38.5-43.75 (110-125%)	43.75-61.25 (125-175%)	61.25-87.5 (175-250%)	>87.5 (>250%)
Number and percent of boluses	0/108 (0.0%)	0/108 (0.0%)	0/108 (0.0%)	0/108 (0.0%)	108/108 (100%)	0/108 (0.0%)	0/108 (0.0%)	0/108 (0.0%)	0/108 (0.0%)	0/108 (0.0%)

3. Occlusion detection

To assess occlusion detection performance and unintended bolus upon occlusion release performance, 16 micropumps were tested. Both aged and unaged lots of pump bases, reservoirs and cannula assembly and pump holder were used.

The following table depicts the typical (average) time to occlusion detection for three different situations when using U-100 insulin.

Table 7: Timing of occlusion detection alarms

	Typical time to occlusion detection	**Maximum time to occlusion detection**
25 U Bolus	1 minute 11 seconds	5 minutes 16 seconds
1.0 U/hr Basal	3 hour 29 minutes	7 hours 45 minutes
0.1 U/hr Basal	26 hours 53 minutes	71 hours

After pumps alarmed, the occlusions were cleared and the total amount of fluid delivered was measured. Typical volumes were less than 3 U.

B. Other Supportive Instrument Performance Characteristics Data

1. Hazard Analysis

A comprehensive hazard analysis was reviewed, in which design inputs and outputs, risks, and risk mitigations for hardware and software associated with proper functioning of the insulin pump were reviewed. The sponsor performed a hazard analysis to account for the unique intended use, design elements, and risks of their ACE pump. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

2. Human Factors

Human factors validation tests were conducted with the Accu-Chek Solo micropump system with interoperable technology. All study participants received training that was consistent with the training that patients would receive with the commercial product. Usability evaluations assessed comprehension and usability of the device for critical device tasks. Results of the study demonstrated that the micropump system is validated for its intended use.

3. Biocompatibility

Biocompatibility testing was performed per FDA Guidance Document: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and FDA special controls for alternate controller enabled infusion pumps for the disposable cassette, pump and the disposable cassette packaging and dust cover. All endpoints were tested adequately, and results were acceptable.

4. Sterility

The Accu-Chek Solo reservoir assembly, cannula assembly and pump holder are provided sterile. These components are terminally sterilized in its final package using Ethylene Oxide and the process has been validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO 11135: 2014.

5. Insulin Compatibility and Stability

The Accu-Chek Solo micropump system was found to be compatible with U-100 insulin Novolog (insulin aspart), Fiasp (insulin aspart), Humalog (insulin lispro) for up to 4 days and with Apidra (insulin glulisine) for up to 2 days.

6. Additional Bench 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. Summaries for reliability, safety, and verification testing follow:

Testing to Support System Reliability
Durability of pumping mechanism
Pump Bolus Button
Buzzer
Inserter
Pump-reservoir interface
Power supply
Against chemical stressors (e.g. sunscreens, insect repellents)

Testing to Support System Safety
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Leakage Testing
Alarms Testing
Data Handling Testing

Pump Activation and Deactivation Testing
Pump/Diabetes Manager Connectivity Testing
User Guide Testing
Incidental Delivery
Worst Case Accuracy

Testing to Support System Verification
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Buzzer Testing
User Guide Testing
Insulin Delivery Verification Testing
Environmental conditions Testing
Ingress protection and protection against sweat
Cleaning Test

7. Electromagnetic Compatibility and Wireless Coexistence

   Electromagnetic compatibility, electromagnetic immunity and wireless coexistence testing was performed for the pump. All tests demonstrated that the device would perform as expected in the home healthcare environment.

8. Basic Safety and Essential Performance (Electrical Safety)

   The sponsor provided verification evidence for compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalent for this device.

9. Data Logging

   The sponsor provided a summary of pump and controller logging capability which enable the device to record critical events including insulin delivery, pump commands and confirmations, connectivity states, malfunctions, and alarms. These were reviewed and found to be adequate.

10. Interoperability

    A plan and approach for interoperability were provided according to the FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices"* and determined to be adequate to support and clearly specify expectations, requirements, and interface specifications to potential interoperable devices. In addition, their plan covered their approach to working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market

reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

The sponsor additionally provided validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were reviewed and found to be adequate.

11. Software and Cybersecurity

Detailed Information on software and cybersecurity of the device was reviewed and found acceptable.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.