510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K233952

B Applicant

Deka Research and Development

C Proprietary and Established Names

DEKA ACE Pump System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	Class II	21 CFR 880.5730 - Alternate Controller Enabled Infusion Pump	CH - Clinical Chemistry
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	CH - Clinical Chemistry

E Purpose for Submission

Modification of the DEKA ACE Pump System cleared in K213536 by replacing the dedicated Android controller with an iOS application installed on the user's personal iPhone and by adding DEKA Loop (K234055) to the pump, which is a ported version of Tidepool Loop (K203689).

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The DEKA ACE Pump System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, ages six and above. 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 bolus calculator is indicated for use for aiding the user in determining the bolus insulin dosage for management of diabetes mellitus based on consumed carbohydrates, operator entered blood glucose, insulin sensitivity, insulin to carbohydrate ratio, target glucose values, and current insulin on board.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The DEKA ACE Pump System is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by their healthcare provider.
- Maintain sufficient diabetes selfcare skills.
- See their healthcare provider regularly.
- Demonstrate adequate carbohydrate-counting skills.

The user must not:

- Have difficulty seeing.
- Have difficulty hearing.
- Have deficient cognitive capabilities.
- Have physical impairments which would make operating the pump or iPhone difficult.

The DEKA ACE Pump System is intended for single-patient use and requires a prescription. The device is designed to use rapid-acting U-100 insulin. The DEKA ACE Pump System is compatible with the following U-100 insulins: Humalog.

The system is Magnetic Resonance Unsafe. Disconnect the pump before entering an MRI scan room. Do not bring the iPhone or pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner can cause the pump and iPhone to move or lead to electric shocks and may result in severe injury.

Do not expose the system to: X-ray, Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) scan, Other exposure to radiation. Disconnect the pump and leave it outside the room prior to these procedures. Failure to do so may lead to harm.

Do not expose the system to: Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or programming, Cardiac Catheterization, Nuclear Stress Test. Users must remove the systems and leave them outside the procedure room prior to these procedures. Failure to do so may lead to harm.

III Device/System Characteristics:

A Device Description:

The DEKA ACE Pump system is a modification of the previously cleared DEKA ACE Pump System. The DEKA ACE Pump System consists of the following components:

- **Pump:** A durable pump embedded with the DEKA Loop, which incorporates fluid delivery algorithms and interfaces to a cassette, external wireless user interface, and iCGM. The pump is powered by a rechargeable lithium ion battery.
- **Cassette:** A single-use pumping cassette that combines microfluidic valves, a pump chamber, insulin reservoir, and Acoustic Volume Sensing (AVS) measurement chamber. The cassette interfaces to a pump and off-the-shelf infusion sets.
- **User interface app:** The DEKA ACE Pump is controlled by the DEKA Loop app, separately cleared under k234055. The DEKA Loop app is an Apple iOS-based Bring Your Own Device (BYOD) App available for user download in Apple's App store. The App is compatible with version 16 of iOS and communicates to the pump using secure BLE wireless communication. The DEKA Loop App is the primary user interface to operate the DEKA ACE Pump System.

The DEKA ACE Pump system includes the following electronic interfaces:

- **Dexcom G6 iCGM:** The DEKA ACE Pump System is compatible with the Dexcom G6 iCGM. The ACE Pump communicates with the iCGM transmitter at a regular interval to provide iCGM sensor data to the iAGC.
- **Halo Cloud:** Halo Cloud is a digital platform that connects the DEKA ACE Pump system to a variety of cloud-related services.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

DEKA ACE Pump System

B Predicate 510(k) Number(s):

K213536

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233952	K213536
Device Trade Name	DEKA ACE Pump System	DEKA ACE Pump System
General Device Characteristic Similarities		

Intended Use/Indications For Use	The device is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, ages six and above. 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 bolus calculator is indicated for use for aiding the user in determining the bolus insulin dosage for management of diabetes mellitus based on consumed carbohydrates, operator entered blood glucose, insulin sensitivity, insulin to carbohydrate ratio, target glucose values, and current insulin on board.	Same
General Device Characteristic Differences		
Intended Use Population	Persons with Diabetes Mellitus ages 6 and above	Persons with Diabetes Mellitus ages 13 and above

V Standards/Guidance Documents Referenced:

- Special controls established under 21 CFR 880.5730 for alternate controller enabled infusion pump
- ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION, 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 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, 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 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes
- ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 11607-1 Second edition 2019-02, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11137-1 First edition 2006-04-15, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]
- IEC/TR 60601-4-2 Edition 1.0 2016-05, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
- AIM Standard 7351731 Rev. 3.00 2021-06-04, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
- IEEE ANSI USEMCSC C63.27-2021, American National Standard for Evaluation of Wireless Coexistence

VI Performance Characteristics (if/when applicable):

A Other Supportive Instrument Performance Characteristics Data:

1. Risk analysis

Risk management activities were reviewed, including identification of essential performance, relevant hazards, failure modes, causes, and risk controls to mitigate the identified failure modes and causes to those failure modes. Risk controls are denoted as requirements, which are verified in testing. The output of risk management activities includes a final risk summary report as well as traceability of hazards to associated risk controls and their verification in the final design. All risks are adequately controlled and all risk control measures have been validated in the final device.

2. Human Factors

Additional human factors validation tests were conducted with the DEKA ACE Pump System. 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 DEKA ACE Pump System is validated for its intended use.

3. Electromagnetic Compatibility and Wireless Coexistence

   Additional 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.

4. Basic Safety and Essential Performance (Electrical Safety)

   The sponsor provided additional verification evidence for the DEKA ACE Pump App and Bring-Your-Own-Device updates in compliance with the IEC 60601-1 and applicable collateral standards. Verification results support the finding of substantial equivalent for this device.

5. Interoperability

   The plan and approach for interoperability with an iCGM remain unchanged from the predicate device. The device has an embedded iAGC algorithm in the Pump software, which eliminates the need for an additional secure digital connection.

6. 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.