March 13, 2024

Deka Research and Development
Paul Smolenski
Regulatory Affairs
340 Commercial Street
Manchester, New Hampshire 03101

Re: K233952
Trade/Device Name: DEKA ACE Pump System
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG, NDC
Dated: December 14, 2023
Received: December 15, 2023

Dear Paul Smolenski:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K233952

Device Name
DEKA ACE Pump System

Indications for Use *(Describe)*
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.

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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510(k) Summary: K233952

Submitter Information

510(k) Sponsor: DEKA Research & Development
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Date Prepared: 2/29/2024

Proposed Device

Common/Usual Name: ACE Pump
Trade/Proprietary Name: DEKA ACE Pump System
Classification Name: Alternate Controller Enabled ACE Pump
Device Classification: 880.5730
Product Code: QFG
Class: II
Device Panel: Clinical Chemistry

Predicate Device

The predicate device for this submission is the DEKA ACE Pump System cleared on 7/25/2023 under 510(k) K213536.

Device Description

The DEKA ACE Pump system is a modification of the previously cleared DEKA ACE Pump System (K213536). The modified device is a wearable alternate controller enabled (ACE) insulin infusion pump (DEKA ACE Pump System) with the addition of an embedded iAGC (DEKA Loop). The user interface is an iOS app that can be downloaded to a user's iPhone.

The updated system is still intended to subcutaneously deliver 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 to receive, confirm, and execute commands. The Pump is intended for single patient, ambulatory use and requires a prescription. The Pump is indicated for use with Humalog U-100 insulin.

The DEKA ACE Pump System is indicated for the management of mellitus in persons six years of age and greater.

The system as described in this submission is able to be integrated with an integrated Continuous Glucose Monitor (iCGM). This submission also details the integration process that was used to incorporate the DEKA Loop iAGC Algorithm onto the DEKA ACE Pump.

The DEKA ACE Pump System consists of the following durable and disposable components:

- Pump: A durable pump that 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.
- DEKA Loop App**:** An iOS mobile application that serves as the primary user face for the system. The DEKA Loop app can be downloaded onto the user's personal iPhone.

The DEKA ACE Pump System is designed to be shipped to users in a kit that also includes infusion sets, needles, syringes, and other materials necessary for use.

Also consistent with the predicate, the DEKA ACE Pump system includes the following electronic interfaces:

- Dexcom G6 iCGM: The DEKA ACE Pump System is compatible with Dexcom G6 iCGMs. Communication between the Dexcom G6 and DEKA ACE Pump is unchanged from the predicate device. The BLE central role on the ACE Pump radio processor connects directly to the Dexcom iCGM transmitter using the sensor's medical slot. 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. These services include:
    - Patient on-boarding and device pairing via secure key transfer
    - Prescription setting downloads to the ACE Pump
    - Event log uploads from the ACE pump to the cloud
    - Remote (OTA) software updates

Information is being supplied in this 510(k) premarket submission to demonstrate that the device is substantially equivalent in safety and effectiveness through comparison of indications for use and technological characteristics to the predicate DEKA ACE Pump System cleared on 7/25/2023 under K213536. As described throughout this submission, the subject DEKA ACE Pump System meets the product definition and all of the Special Controls defined in 21CFR 880.5730 for Alternate Controller Enabled Insulin Infusion Pumps, Product Code QFG.

Substantial Equivalence Discussion

Intended Use Comparison

The table below compares the intended use of the subject device to that of the predicate device:

Characteristic	Predicate Device	Subject Device
Indications 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 13 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.	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.
Prescription Use	Yes	Yes
Intended Population	Persons with Diabetes Mellitus ages 13 and above	Persons with Diabetes Mellitus ages 6 and above
Environment of Use	In professional healthcare facilities and home healthcare environments	In professional healthcare facilities and home healthcare environments

Discussion of differences in Indications of Use statements
The subject 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 6 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.

The predicate's indications for use from K213536 are as follows:
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 13 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.

Discussion of differences in intended populations
Both the predicate and subject device are intended for use in persons with Diabetes Mellitus. The predicate device is indicated for ages 13 and above and the subject device is indicated for ages 6 and above. The difference in the lower age limit does not impact the safety and effectiveness of the device for its indicated use. The risk management documentation has been updated to reflect this modification. Human Factors testing demonstrates equivalent safety and effectiveness for the indicated population.

Discussion of differences in environments of use
Both the predicate and subject devices are intended to be used in professional healthcare facilities and home healthcare environments. There are no differences in the environments of use.

Comparison of Technological Characteristics
The below table compares the technological characteristics of the subject device with those of the predicate. If a technological characteristic differs, an assessment of why the difference does not introduce new or different questions of safety or effectiveness is stated.

Substantial Equivalence Table
The table below compares the intended use and technological characteristics of the subject device with that of the predicate device:

Characteristic	Predicate Device	Subject Device	Equivalence
Device Classification Regulation and Product Code	Alternate Controller Enabled Infusion Pump cleared under 21 CFR 880.5730, Product Code QFG	Alternate Controller Enabled Infusion Pump submitted under 21 CFR 880.5730, Product Code QFG	Same
Indications 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 13 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.	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.	The difference in the lower age limit does not impact the safety and effectiveness of the device for its indicated use. The risk management documentation has been updated to reflect this modification. Human Factors testing demonstrates equivalent safety and effectiveness for the indicated population.

Characteristic	Predicate Device	Subject Device	Equivalence
Prescription Use	Yes	Yes	Same
Intended Population	13 years and above	6 years and above	The difference in the lower age limit does not impact the safety and effectiveness of the device for its indicated use. The risk management documentation has been updated to reflect this modification. Human Factors testing demonstrates equivalent safety and effectiveness for the indicated population.
Patient Environment	On-body wearable ambulatory pump	On-body wearable ambulatory pump	Same
Environment of Use	In professional healthcare facilities and home environments	In professional healthcare facilities and home environments	Same
Primary User Interface	Remote Interface hand-held controller	iOS app downloaded to a user's iPhone	The modifications to the user interface do not impact safety or effectiveness. Both controllers provide the same level of functionality and Human Factors testing demonstrates equivalent safety and effectiveness for the indicated population.
Delivery Method	Microprocessor controlled micro-dosing pump mechanism supplemented with Acoustic Volume Sensor (AVS) feedback for monitoring delivery accuracy	Microprocessor controlled micro-dosing pump mechanism supplemented with Acoustic Volume Sensor (AVS) feedback for monitoring delivery accuracy	Same
Insulin Basal Rate Delivery Range	0 Units/hour - 30 Units/hour	0 Units/hour - 30 Units/hour	Same

Characteristic	Predicate Device	Subject Device	Equivalence
Insulin Bolus Delivery Range	Programmable between 0.05 - 25.00 Units in 0.01 Unit increments	Programmable between 0.05 - 25.00 Units in 0.01 Unit increments	Same
Basal Accuracy	See "Delivery Accuracy" below	See "Delivery Accuracy" below	Same
Bolus Accuracy	See "Delivery Accuracy" below	See "Delivery Accuracy" below	Same
Bolus Volume after Occlusion Release	No more than 0.74 Units	No more than 0.74 Units	Same
Time to Occlusion Alarm	10 min (Bolus); 3 hours (Basal, 1 U/hr); 6 hours (Basal, 0.1 U/hr)	10 min (Bolus); 3 hours (Basal, 1 U/hr); 6 hours (Basal, 0.1 U/hr)	Same
Material Biocompatibility	Compliant with ISO-10993	Compliant with ISO-10993	Same
Cartridge/Cassette Shelf Life	1 year	1 year	Same
Ingress Protection	IP28, indicating protection from continuous immersion in water. The pump can tolerate immersion to depths of up to 12 feet (3.7 m) for 1 hour.	IP28, indicating protection from continuous immersion in water. The pump can tolerate immersion to depths of up to 12 feet (3.7 m) for 1 hour.	Same
Applicable Safety Standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • ISO 10993-1 • ISO 14971	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-1-10 • IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • ISO 10993-1 • ISO 14971	IEC 60601-1-10 evaluation was included in the subject device submission due to the integration of DEKA Loop.
Power Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	Same

Characteristic	Predicate Device	Subject Device	Equivalence
Pump Storage Conditions	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity of 15% to 90%	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity of 15% to 90%	Same
Operating Conditions	Temperatures of 5 °C (41 °F) to 40 °C (104 °F) Non-condensing humidity of 15% to 90%	Temperatures of 5 °C (41 °F) to 40 °C (104 °F) Non-condensing humidity of 15% to 90%	Same
System User Feedback	Visual, audio, and vibratory	Visual, audio, and vibratory	Same
Battery Operating Time	72 hours	72 hours	Same

The table below compares the intended use and technological characteristics of the subject bolus calculator with that of the predicate bolus calculator:

Characteristic	Predicate Device (Bolus Calculator – K213536)	Subject Device (Bolus Calculator)	Equivalence
Intended Use	The bolus calculator aids the user in determining the insulin bolus dosage needed based on carbohydrates ingested, most recent blood glucose reading, insulin sensitivity, insulin to carbohydrate ratio, target blood glucose values, and Insulin on Board (IOB).	The bolus calculator aids the user in determining the insulin bolus dosage needed based on carbohydrates ingested, most recent blood glucose reading, insulin sensitivity, insulin to carbohydrate ratio, target blood glucose values, and Insulin on Board (IOB).	Same
Normal and Extended Bolus	A Correction Bolus must be delivered as a Normal Bolus; Meal	A Correction Bolus must be delivered as a Normal Bolus; Meal	Same

	Boluses can be delivered as normal or extended	Boluses can be delivered as normal or extended	
Correction Bolus	Positive correction occurs if blood glucose is higher than the "high target" and a negative correction bolus occurs if blood glucose is lower than the "low target"	Positive correction occurs if blood glucose is higher than the "high target" and a negative correction bolus occurs if blood glucose is lower than the "low target"	Same
Preliminary Meal Bolus Calculation	Carb Intake/Insulin-to-Carb Ratio	Carb Intake/Insulin-to-Carb Ratio	Same
Suggested Bolus Rounded to	Nearest 0.01 U	Nearest 0.01 U	Same
Calculated IOB Rounded to	Nearest 0.01 U	Nearest 0.01 U	Same
User Inputs in Bolus Calculator	• Blood Glucose level • Carbs • Insulin to Carbohydrate (IC) Ratio • Insulin Sensitivity (Correction Factor) • High Target (BG) • Low Target (BG)	• Blood Glucose level • Carbs • Insulin to Carbohydrate (IC) Ratio • Insulin Sensitivity (Correction Factor) • High Target (BG) • Low Target (BG)	Same
Maximum Bolus Size	Manually set by user	Manually set by user	Same
Primary User Interface	Screen on Remote Interface	Screen on iPhone	Equivalent
User Inputs to Calculation (after set-up)	Carbs, Blood Glucose Level	Carbs, Blood Glucose Level	Same
Calculator Outputs	Recommended Bolus Amount	Recommended Bolus Amount	Same
Labeling	User Interface Workflow described in User Guide	User Interface Workflow described in User Guide	Same

Non-Clinical / Performance Testing:
Performance testing was performed in order to establish substantial equivalence in terms of both safety and effectiveness, and to ensure the subject device met all applicable Special Controls. Performance testing from the predicate submission, K213536, is applicable to the subject submission.

Testing was performed utilizing the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-10, IEC 60601-1-11, IEC 60601-2-24, IEC 62304.

Human Factors was performed for the incorporation of DEKA Loop and the updated User Interface.

Clinical Study
No clinical data was obtained in support of this premarket submission.

Design Control
The DEKA ACE Pump System was specified and developed by DEKA. DEKA complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as ISO 13485.

Conclusion
The DEKA ACE Pump System Infusion Pump is substantially equivalent to the predicate cleared on 7/25/2023 in K213536. The differences, summarized in this submission, do not raise different questions of safety or effectiveness. The performance of the device is supported by DEKA's design control process which included non-clinical testing and risk management activities. The device meets all Special Controls for this product type as required by 21 CFR 880.5730 for Alternate Controller Enabled Insulin Infusion Pumps, Product Code QFG.