510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K213536

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 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 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.

C Special Conditions for Use Statement(s):

This device is 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 team.
- Maintain sufficient diabetes self- care skills.
- See their healthcare team regularly.
- Demonstrate adequate carbohydrate-counting skills (preferred, not required).

The user must not:

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

The device must be removed before Magnetic Resonance Imaging (MRI). Exposure to MRI may cause the pump and controller to move or lead to electric shocks and may result in severe injury.

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.

III Device Description

The DEKA ACE Pump is an Alternate Controller Enabled (ACE) infusion pump 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 system is able to be integrated with a Dexcom G6 interoperable Continuous Glycemic Controller (iCGM).

The DEKA ACE Pump System consists of the following components:

- **Pump:** A durable pump that incorporates fluid delivery algorithms and interfaces to an DEKA ACE Pump cassette, Remote Interface, iCGM, and iAGC. 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 an DEKA ACE Pump and off-the-shelf infusion set.
- **Remote Interface** (Controller): A wireless controller that serves as the user interface to the DEKA ACE Pump system. This includes a large color touch display for ease of use.

The Controller is used in conjunction with the pump, Dexcom G6 CGM, and blood glucose monitor devices to program and monitor insulin delivery and blood glucose levels in your body.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

t:slim X2 insulin pump with interoperable technology

B Predicate 510(k) Number(s):

DEN180058

C Comparison with Predicate(s):

Device & Predicate Device(s):	K213536	DEN180058
Device Trade Name	DEKA ACE Pump System	t:slim X2 insulin pump 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 Humalog	U-100 Insulin. System has been tested with NovoLog and Humalog.
Intended Population	Persons with Diabetes Mellitus ages 13 and up	Persons with Diabetes Mellitus ages 6 and up
Insulin Basal Rate Delivery Range	0 – 30 U/hour	0 – 15 U/hour
Insulin Bolus Delivery Range	Programmable from 0.05 - 25.00 Units in 0.01 Unit increments.	0.01 U at volumes greater than 0.05 U, Max bolus volume 25 U

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 "General Principles of Software Validation" dated January 11, 2002
- 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 10993-4:2002(A-2006) Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood
- 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 14971 Second Edition 2007-03-01 Medical Devices – Application of Risk Management to Medical Devices
- IEC 60601-1:2005+AMD1:2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Ed. 4.0 b: 2014 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 Ed. 3.1 b. 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-8 Ed. 2.1 b: 2012 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 Issued: 2015/01/20 Ed.2 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 Ed. 1.0 Medical Devices – Part 1: Application Of Usability Engineering To Medical Devices
- ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 11137-1: 2006 Sterilization of health care productions – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 11137-2: 2013 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

VI Performance Characteristics:

A. Analytical Performance

1. Basal delivery accuracy

To assess basal delivery accuracy, 32 pumps were tested by delivering at minimum, intermediate, and maximum basal rates (0.1, 1.0, and 30 U/hr). Sixteen of the pumps were unaged and 16 had been aged to simulate three years of regular use. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging. 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 (30 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]	0.12 U [0.09, 0.17]	0.62 U [0.57, 0.66]	1.22 U [1.16, 1.31]

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]	1.02 U [0.98, 1.09]	6.05 U [5.84, 6.22]	12.07 U [11.73, 12.33]

Table 3: Amount of fluid delivered after 1, 6, and 12 hours with 30 U/hr (high) basal rate setting

30 U/hr Basal Duration	**1 hour**	**6 hours**
Total expected delivery volume	**30 U**	**180 U**
Median amount delivered [min, max]	30.16 U [29.80, 30.61]	181.05 U [178.94, 184.46]

2. Bolus delivery accuracy

To assess bolus delivery accuracy, 32 pumps were tested by delivering at minimum, intermediate, and maximum bolus volumes (0.05, 5.0, and 25 U). Each pump delivered 25 minimum and intermediate volume boluses and 7 maximum volume boluses interspersed during periods of active basal delivery. For each pump and cassette combination, a head height, orientation, infusion set, and insulin type was chosen. An approximately even distribution of parameters were used across the 32 combinations. Sixteen of the pumps were unaged and sixteen had been aged to simulate three years of regular use. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging.

Tables 4-6 below show the number (and %) of boluses within the specified range of each target bolus volume.

Table 4: Amount of fluid delivered after a 0.05 U bolus request (n=800 boluses)

Units delivered after a 0.05 U bolus request (% of commanded units)										
	<0.0125 (<25%)	0.0125 - 0.0375 (25-75%)	0.0375-0.045 (75-90%)	0.045-0.0475 (90-95%)	0.0475-0.0525 (95-105%)	0.0525-0.0550 (105-110%)	0.055-0.0625 (110-125%)	0.0625-0.0875 (125-175%)	0.0875-0.125 (175-250%)	>0.125 (>250%)
Number and percent of boluses	0/800 (0.0 %)	53/800 (6.6 %)	202/800 (25.3 %)	107/800 (13.4 %)	278/800 (34.8 %)	80/800 (10.0 %)	69/800 (8.6 %)	11/800 (1.4 %)	0/800 (0 %)	0/800 (0 %)

Table 5: Amount of fluid delivered after a 5.0 U bolus request (n=800 boluses)

Units delivered after a 5.0 U bolus request (% of commanded units)										
	<1.25 (<25%)	1.25-3.75 (25-75%)	3.75-4.50 (75-90%)	4.50-4.75 (90-95%)	4.75-5.25 (95-105%)	5.25-5.50 (105-110%)	5.50-6.25 (110-125%)	6.25-8.75 (125-175%)	8.75-2.50 (175-250%)	>12.50 (>250%)
Number and percent of boluses	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	800/800 (100%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)

Table 6: Amount of fluid delivered after a 25 U bolus request (n=224 boluses)

Units delivered after a 25.0 U bolus request (% of commanded units)										
	<6.25 (<25%)	6.25-18.75 (25-75%)	18.75-22.5 (75-90%)	22.5-23.75 (90-95%)	23.75-26.25 (95-105%)	26.25-27.5 (105-110%)	27.5-31.25 (110-125%)	31.25-43.75 (125-175%)	43.75-62.5 (175-250%)	>62.5 (>250%)
Number and percent of boluses	0/224 (0.0%)	0/224 (0.0%)	0/224 (0.0%)	0/224 (0.0%)	222/224 (99.1%)	2/224 (0.9%)	0/224 (0.0%)	0/224 (0.0%)	0/224 (0.0%)	0/224 (0.0%)

3. Occlusion detection

To assess occlusion detection performance and unintended bolus upon occlusion release performance, 32 pumps were tested. Sixteen of the pumps were unaged and 16 had been aged. For both aged and unaged pumps, eight pumps were tested with an unaged cassette, and eight with a cassette which underwent one year of accelerated aging.

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**
2.0 U Bolus	1 minute 52 seconds	2 minutes 17 seconds
1.0 U/hr Basal	19 minutes 33 seconds	27 minutes 22 seconds
0.1 U/hr Basal	1 hour 55 minutes	3 hours 9 minutes

After pumps alarmed, the occlusions were cleared and the total amount of fluid delivered was measured. Typical volumes were 0.25 U, and maximum volumes were 0.4 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 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. Biocompatibility

Biocompatibility testing was performed per ISO 10993-1:2018, 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 sterility information was reviewed and found to be acceptable.

5. Insulin Compatibility and Stability

The DEKA ACE Pump system is compatible with U-100 insulin Humalog (insulin lispro) for up to 3 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
Acoustic Volume Sensor
Pump Button
Pump Alarm
Pump and cassette mating
Pump Battery
Charger
Power Button
Remote Interface

Testing to Support System Safety
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Design specific tests: Volume Cross Checks, Inter and Intra Delivery Leaks
Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing

Pump/Controller Connectivity Testing
User Guide Testing
Insulin Delivery Verification Testing
Incidental Delivery
Worst Case Accuracy
Fault Insertion Testing

Testing to Support System Verification
Environmental Safety Testing to 60601-1-11
Safety and Essential Performance Testing to 60601-1
Occlusion Detection Testing
Alarms Testing
Data Handling Testing
Pump Activation and Deactivation Testing
Pump/Controller Connectivity Testing
User Guide Testing
Insulin Delivery Verification Testing
Environmental conditions Testing

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 - Guidance for Industry and Food and Drug Administration Staff"* 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.