July 25, 2023

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

Re: K213536
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: November 5, 2021
Received: November 5, 2021

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 (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 Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K213536

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 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.

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: K213536

Submitter Information

510(k) Sponsor: DEKA Research & Development
340 Commercial Street
Manchester, NH 03101

Contact Person: Paul Smolenski
Regulatory Affairs
DEKA Research & Development
Phone: (603) 669-5139
Fax: (603) 624-0573
psmolenski@dekaresearch.com

Date Prepared: 07/24/2023

Proposed Device

Common/Usual Name: ACE Pump
Trade/Proprietary Name: DEKA ACE Pump System
Classification Name: Alternate Controller Enabled ACE Pump; Calculator, Drug Dose
Device Classification: 880.5730 ; 868.1890
Product Code: QFG ; NDC
Class: II
Device Panel: Clinical Chemistry

Predicate Device

The predicate device for this submission is the Tandem t:Slim X2 insulin pump with interoperable technology granted under De Novo DEN180058.

Device Description

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 system as described in this submission is able to be integrated with a Dexcom G6 interoperable Continuous Glycemic Controller (iCGM). This submission also details the integration process that can be used to incorporate an iAGC.

The DEKA ACE Pump System consists of the following components:

1. **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.

2. **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.
3. **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.

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 Tandem t:Slim X2 insulin pump with interoperable technology granted on 12/03/2019 under De Novo DEN180058. As described throughout this submission, the subject DEKA ACE Pump system meets the product definition and all of the Special Controls defined in DEN180058 and 21 CFR 880.5730 for Alternate Controller Enabled Insulin Infusion Pumps, Product Code QFG.

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.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a summation matrix of the intended use between the new device and those of the current device:

Characteristic	Predicate	Device
Indications for Use	The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the 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 or Humalog U-100 insulin. The Pump is indicated for use in	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

	individuals 6 years of age and greater.	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 Only or Over the Counter	Prescription Only	Same
Intended Population	Persons with Diabetes Mellitus Ages 6 and up	Persons with Diabetes Mellitus Ages 13 and up
Environment of Use	In professional healthcare facility and home healthcare environments	Same

Discussions of differences in Indications of Use statement

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 predicate's indications for use from DEN180058 are as follows:
The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the 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 or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.

Discussions of differences in intended population

Both the predicate and subject device are intended for use in persons with Diabetes Mellitus. The predicate device is indicated for ages 6 and older and the subject device is indicated for ages 13 and older. The difference in the lower age limit does not impact the safety and effectiveness of the device for its indicated use. Testing demonstrates equivalent safety and effectiveness for the

indicated population.

Discussions of differences in environment of use

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

Comparison of Technological Characteristics with the Predicate Device
The below table compares the characteristics of the subject device to the predicate, t:slim X2 insulin infusion pump, and includes an assessment of differences between them and why the differences between the subject device and the predicate device do not introduce new or different questions of safety or effectiveness.

Substantial Equivalence Discussion

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, Procode QFG	Alternate Controller Enabled Infusion Pump submitted under 21 CFR 880.5730, Procode QFG	Same
Indications for Use	The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the 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 or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.	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-	Indications for use of the DEKA ACE Pump System are equivalent to the predicate. Indications for use of the bolus calculator are equivalent to other devices with this product code.

Characteristic	Predicate Device	Subject Device	Equivalence
		entered blood glucose, insulin sensitivity, insulin to carbohydrate ratio, target glucose values, and current insulin on board.	
Prescription Use	Yes	Yes	Same
Intended Population	6 years and older	13 years and older	The difference in the lower age limit does not impact the safety and effectiveness of the device for its indicated use. 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
Delivery Method	Micro-dosing threaded cartridge pump	Microprocessor controlled Micro-dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy	No impact to safety or effectiveness. Subject device meets all Special Controls requirements. Delivery method has been found SE to ambulatory pumps through clearance of reference device.
Insulin Basal Rate Delivery Range	0 units /hour- 15units/hour	0 units/hour - 30 units/hour	No impact on safety or effectiveness. Subject device meets all Special Controls requirements across the entire delivery rate range.
Insulin Bolus Delivery Range	0.01 U at volumes greater than 0.05 U units, Max Bolus Volume 25 U	Programmable from 0.05 - 25.00 Units in 0.01 Unit increments.	Same

Characteristic	Predicate Device	Subject Device	Equivalence
Basal Accuracy	See Delivery Accuracy Comparison Below	See Delivery Accuracy Comparison Below	No impact on safety or effectiveness. Subject device meets all Special Controls requirements across the entire delivery rate range.
Bolus Accuracy	See Delivery Accuracy Comparison Below	See Delivery Accuracy Comparison Below	No impact to safety or effectiveness. Subject device meets all Special Controls requirements.
Bolus Volume after Occlusion Release	Less than 3 Units	No more than 0.74 units	No impact to safety or effectiveness. Subject device meets all Special Controls requirements.
Time to occlusion alarm	3 min (Bolus); 2 hours (Basal, 2 U/hr); 36 hours (Basal, 0.1 U/hr):	10 min (Bolus); 3 hours (Basal, 1 U/h); 6 hours (Basal, 0.1 U/hr)	No impact to safety or effectiveness. Subject device meets all Special Controls requirements.
Material Biocompatibility	Compliant with ISO-10993	Compliant with ISO-10993	Same
Cartridge/Cassette Shelf Life	2 years	1 year	Performance testing over the one year shelf life of the cassette indicates that the cassette remains safe and effective.
Ingress Protection	IPX7: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes	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.	The higher level of ingress protection than predicate meets use model requirements.
Applicable Safety Standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-8	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-8	Same

Characteristic	Predicate Device	Subject Device	Equivalence
	• IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • ISO 10993-1 • ISO 14971	• IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • ISO 10993-1 • ISO 14971	
Power Source	Rechargeable Lithium Polymer Battery	Rechargeable Lithium Ion Battery	Same
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity 15% to 90%	No impact to safety or effectiveness. Subject device meets all Special Controls requirements.
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing	Temperatures of 5 °C (41 °F) to 40 °C (104 °F) Non-condensing humidity of 15% to 90%	No impact to safety or effectiveness. Subject device meets all Special Controls requirements.
System User Feedback	Visual, audible, and vibratory	Visual, audio, and vibratory	Same
Battery Operating Time	4 – 7 days	72 hours	No impact to safety or effectiveness. Subject device meets all Special Controls requirements.

Basal and Bolus Accuracy Comparison

Below is a comparison of the basal and bolus accuracies of the subject and predicate devices, as reported in their respective User Guides per the ACE Pump Special controls.

Tandem (DEN180058) Basal Accuracy:

0.1 U/hr Basal Accuracy

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
1 hour	0.12	0.09	0.16
6 hours	0.67	0.56	0.76
12 hours	1.24	1.04	1.48

2.0 U/hr Basal Accuracy

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
1 hour	2.1	2.1	2.2
6 hours	12.4	12.0	12.8
12 hours	24.3	22.0	24.9

15.0 U/hr Basal Accuracy

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
1 hour	15.4	14.7	15.7
6 hours	90.4	86.6	93.0
12 hours	181	175	187

DEKA ACE Pump Basal Accuracy:

0.1 U/hr Basal Accuracy

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
1 hour	0.12	0.09	0.17
6 hours	0.62	0.57	0.66
12 hours	1.22	1.16	1.31

1 U/hr Basal Accuracy

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
1 hour	1.02	0.98	1.09

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
6 hours	6.05	5.84	6.22
12 hours	12.07	11.73	12.33

30 U/hr Basal Accuracy

Interval	Average Interval (U)	Minimum (U)	Maximum (U)
1 hour	30.16	29.80	30.61
6 hours	181.05	178.94	184.46

Tandem (DEN180058) Bolus Accuracy:

	0.05U bolus accuracy									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number of boluses	21 / 800	79 / 800	63/ 800	34 / 800	272 / 800	180 / 800	105 / 800	29 / 800	17 / 800	0 / 800
% of boluses	2.6%	9.9%	7.9%	4.3%	34.0%	22.5%	13.1%	3.6%	2.1%	0.0%

	2.5U bolus accuracy									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number of boluses	9 / 800	14 / 800	11 / 800	8 / 800	753 / 800	5 / 800	0 / 800	0 / 800	0 / 800	0 / 800
% of boluses	1.1%	1.8%	1.4%	1.0%	94.1%	0.6%	0.0%	0.0%	0.0%	0.0%

	25U bolus accuracy									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number of boluses	0 / 256	0 / 256	1 / 256	3 / 256	252 / 256	0 / 256	0 / 256	0 / 256	0 / 256	0 / 256

	25U bolus accuracy									
% of boluses	0.0%	0.0%	0.4%	1.2%	98.4%	0.0%	0.0%	0.0%	0.0%	0.0%

DEKA ACE Pump Bolus Accuracy:

	0.05U bolus accuracy									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number of boluses	0 / 800	53 / 800	202 / 800	107 / 800	278 / 800	80 / 800	69 / 800	11 / 800	0 / 800	0 / 800
% of boluses	0.0%	6.6%	25.3%	13.4%	34.8%	10.0%	8.6%	1.4%	0.0%	0.0%

	5U bolus accuracy									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number of boluses	0 / 800	0 / 800	0 / 800	0 / 800	800 / 800	0 / 800	0 / 800	0 / 800	0 / 800	0 / 800
% of boluses	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%

	25U bolus accuracy									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number of boluses	0 / 224	0 / 224	0 / 224	0 / 224	222 / 224	2 / 224	0 / 224	0 / 224	0 / 224	0 / 224
% of boluses	0.0%	0.0%	0.0%	0.0%	99.1%	0.9%	0.0%	0.0%	0.0%	0.0%

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 was organized into the categories described below.

Nominal Basal Accuracy
Nominal Bolus Accuracy
Worst Case Accuracy
Occlusions
Fault Insertion
Sound Testing
Incidental Delivery
Reliability
Drug Compatibility and Particulate Testing
System Level Functionality
Battery Performance
Environmental Conditions

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

Clinical Study

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

Design Control

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

Conclusion

The DEKA ACE Pump System is substantially equivalent to the t:slim X2 insulin pump with interoperable technology. The differences summarized in this submission do not raise different questions of safety and effectiveness. The performance of the device is supported by DEKA's design control process which included non-clinical testing and risk management activities. The DEKA ACE Pump System complies with the ACE Pump Special Controls as established in DEN180058.