March 13, 2024

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

Re: K234055
Trade/Device Name: DEKA Loop
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable Automated Glycemic Controller
Regulatory Class: Class II
Product Code: QJI
Dated: December 21, 2023
Received: December 22, 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)*
K234055

Device Name
DEKA Loop

Indications for Use *(Describe)*
DEKA Loop is intended for use with compatible integrated continuous glucose monitors (iCGM) and the DEKA alternate controller enabled (ACE) insulin infusion pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend, and with the user's confirmation, control the delivery of correction boluses when glucose values are predicted to exceed user configurable thresholds.

DEKA Loop is intended for the management of Type 1 diabetes mellitus in persons six years of age and greater.

DEKA Loop is intended for single patient use and requires a prescription.

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: K234055

Submitter Information

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

Proposed Device

Common/Usual Name: DEKA Loop
Trade/Proprietary Name: DEKA Loop
Classification Name: interoperable Automated Glycemic Controller
Device Classification: 21 CFR 862.1356
Product Code: QJI
Class: II
Device Panel: Clinical Chemistry

Predicate Device

The predicate device for this submission is Tidepool Loop cleared in K203689.

Device Description

DEKA Loop is an interoperable Alternate Glycemic Controller (iAGC) and works to control an ACE (Alternate Controller Enabled) insulin pump to automatically increase, decrease, and suspend delivery of basal insulin based on readings from an iCGM (integrated continuous glucose monitor) and glucose values predicted by DEKA Loop. DEKA Loop can also recommend, and with the user's confirmation, control the delivery of correction boluses when glucose values are predicted to exceed user configurable thresholds. It is controlled by an iOS app that is downloaded to a user's iPhone.

Intended Use

DEKA Loop is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend and deliver correction boluses when glucose values are predicted to exceed user configurable thresholds. DEKA Loop is intended for the management of Type 1 diabetes mellitus in persons six years of age and greater. DEKA Loop is intended for single patient use and requires a prescription.

Technological Characteristics
DEKA Loop is used with an ACE pump and an iCGM to deliver basal insulin.

Performance Data
Software verification and validation testing was performed per FDA's guidance document, Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification 510(k) Submissions Guidance. Additionally, in-silico software challenge testing demonstrated clinical equivalence to the predicate device.

Substantial Equivalence

DEKA Loop is substantially equivalent to the predicate device, Tidepool Loop, as cleared in K203689. The table below shows a comparison of the technological, functional, and performance characteristics between the subject and predicate devices.

Characteristic	Predicate Device	Subject Device	Explanation of Differences
Device Classification Regulation and Product Code	Interoperable Automated Glycemic Controller, 21 CFR 862.1356, Procode QJI	Interoperable Automated Glycemic Controller, 21 CFR 862.1356, Procode QJI	Same
Indications for Use	Tidepool Loop, a mobile application with algorithm technology, is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) insulin infusion pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend, and with the user's confirmation, control the delivery of correction boluses when glucose values are predicted to exceed user configurable thresholds. Tidepool Loop is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. Tidepool Loop is intended for single patient use.	DEKA Loop is intended for use with compatible integrated continuous glucose monitors (iCGM) and the DEKA alternate controller enabled (ACE) insulin infusion pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend, and with the user's confirmation, control the delivery of correction boluses when glucose values are predicted to exceed user configurable thresholds. DEKA Loop is intended for the management of Type 1 diabetes mellitus in persons six years of age and greater. DEKA Loop is intended for single patient use and requires a prescription.	Equivalent. DEKA Loop is integrated into the DEKA ACE Pump System.

Characteristic	Predicate Device	Subject Device	Explanation of Differences
	Tidepool Loop is Rx - For Prescription Use Only.		
Prescription Use	Yes	Yes	Same
Intended Population	Type 1 diabetes mellitus in persons six years of age and greater.	Type 1 diabetes mellitus in persons six years of age and greater.	Same
Patient Environment	On-body wearable ambulatory pump	On-body wearable ambulatory pump	Same
Environment of Use	Home environments	Home environments	Same
Number of Users	Single user only	Single user only	Same
Technological Characteristics			
Principle of Operation	Tidepool Loop predicts glucose levels up to 6 hours in the future (the approximate duration of insulin action for U-100 rapid-acting insulin) based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and exercise) and uses that prediction to adjust insulin delivery. Tidepool Loop can be used to adjust or suspend basal insulin delivery every 5 minutes and deliver correction boluses of insulin based on actual and predicted CGM sensor readings. Users must manually deliver meal boluses they can calculate using the Tidepool Loop Bolus Recommendation Tool	DEKA Loop predicts glucose levels up to 6 hours in the future (the approximate duration of insulin action for U-100 rapid-acting insulin) based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and exercise) and uses that prediction to adjust insulin delivery. DEKA Loop can be used to adjust or suspend basal insulin delivery every 5 minutes and deliver correction boluses of insulin based on actual and predicted CGM sensor readings. Users must manually deliver meal boluses they can calculate using the DEKA Loop Bolus Recommendation Tool	Same

Characteristic	Predicate Device	Subject Device	Explanation of Differences
	(TLBRT) and can manually adjust insulin delivery (change basal rates and deliver insulin boluses) when Tidepool Loop is active.	(DLBRT) and can manually adjust insulin delivery (change basal rates and deliver insulin boluses) when DEKA Loop is active.	
Type of Algorithm	Hybrid Closed Loop – predictive control	Hybrid Closed Loop – predictive control	Same
Compatible iCGM	Dexcom G6	Dexcom G6	Same
Compatible ACE Pump	An ACE pump that has the specifications and meets the pre-specified acceptance criteria for software, cybersecurity, device interoperability, human factors, labeling, and training materials as described in SOP-0016, "Tidepool Loop Connected Device Integration and Validation Process and Plan," and SOP-0018, "Tidepool Loop Regulatory Determination Process." Tidepool Loop must not be distributed until the pre-specified acceptance criteria in the SOPs are met.	DEKA ACE Pump System	Equivalent. Both require cleared ACE Pumps. In the DEKA ACE Pump System, the integration aspects of the predicate device are addressed by embedding DEKA Loop into the DEKA ACE Pump System.
Device Design or Material	Tidepool Loop is a mobile application and a Software as Medical Device (SaMD) installed on a host mobile device.	DEKA Loop is embedded in the DEKA ACE Pump. The user interface for DEKA Loop is the DEKA Loop App iOS application.	Equivalent. DEKA Loop is embedded in the DEKA ACE pump instead of a host mobile device. The user interface for both systems is an iOS application. Both the subject and predicate devices have equivalent risks and mitigations for each use

Characteristic	Predicate Device	Subject Device	Explanation of Differences
			profile. No new or modified risks.
Algorithm Platform	iPhone	DEKA ACE Pump System	Equivalent. Both the subject and predicate devices have equivalent risks and mitigations for each use profile. No new or modified risks.
Insulin Compatibility	Novolog or Humalog U-100	Novolog or Humalog U-100	Same
Functional Characteristics			
User-controlled Target Range Settings	Customizable settings Correction Range: 87 - 180 mg/dL Pre-Meal Range: Glucose Safety Limit (which can be set from 67-110 mg/dL) - 130 mg/dL Workout Range: the higher of 87 mg/dL or the Glucose Safety Limit (which can be set from 67-110 mg/dL) - 250 mg/dL	Customizable settings Correction Range: 87 - 180 mg/dL Pre-Meal Range: Glucose Safety Limit (which can be set from 67-110 mg/dL) - 130 mg/dL Workout Range: the higher of 87 mg/dL or the Glucose Safety Limit (which can be set from 67-110 mg/dL) - 250 mg/dL	Same
Auto-populating bolus recommendation based on iCGM value: • In closed loop mode • In open loop mode	Yes No	Yes No	Same

Characteristic	Predicate Device	Subject Device	Explanation of Differences
Data List and Logging	Yes	Yes	Same
Daily Activity Records	Yes	Yes	Same
Average Data Display	Yes	Yes	Same
Changing Pump Settings	Yes	Yes	Same
Invite others to view data through authorization	Yes	Yes	Same
Password Required	Yes	Yes	Same
Performance Characteristics			
Bench Performance	Tidepool Loop performance was verified and validated through software verification testing.	DEKA Loop performance was verified and validated through software verification testing.	Same
Clinical Performance	Tidepool Loop clinical performance is supported by representative 1,250 participants in a 15 months duration real-world, observational, single arm study of DIY Loop including both pediatric and adult participants.	In silico testing.	Equivalent. In silico testing proves that the DEKA Loop algorithm is clinically equivalent to the Tidepool Loop Algorithm.
Risk Assessment	Tidepool Loop performed Risk Assessment including detailed hazard analysis based on ISO 14971.	DEKA Loop performed Risk Assessment including detailed hazard analysis based on ISO 14971.	Same
Labeling			
Training	Tidepool Loop includes mandatory in-app learning and setup (user training) before the user can use Tidepool Loop.	Training of features related to DEKA Loop is associated with the DEKA ACE Pump System.	Equivalent. Training on features associated with the integration of DEKA Loop within the DEKA ACE

Characteristic	Predicate Device	Subject Device	Explanation of Differences
			Pump System and the impact on safety and effectiveness were evaluated through Human Factors testing and found to have no impact.
User Guide	Tidepool Loop electronic User Guide also includes all special controls, clinical performance information and other information needed per cybersecurity and interoperability requirements.	Labeling related to DEKA Loop is associated with the DEKA ACE Pump System. The DEKA ACE Pump System user guide includes all special controls, clinical performance information and other information needed per cybersecurity and interoperability requirements.	Equivalent.

Conclusion

DEKA Loop is substantially equivalent to the predicate Tidepool Loop cleared in K203689. 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 862.1356 for interoperable Automated Glycemic Controllers, Product Code QJI.