April 2, 2025

DEKA Research & Development Corp.
William Calhoun
Regulatory Affairs Project Manager
340 Commercial Street
Manchester, New Hampshire 03101

Re: K250930
Trade/Device Name: twiist system
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG, NDC
Dated: March 27, 2025
Received: March 28, 2025

Dear William Calhoun:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division Director
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)*
K250930

Device Name
twiist system

Indications for Use *(Describe)*
The twiist 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 twiist system 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary for K250930

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

Submitter Information

510(k) Sponsor	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person(s)	Paul Smolenski (primary), William Calhoun (alternate) Regulatory Affairs Phone: (603) 669-5139 Fax: (603) 624-0573 psmolenski@dekaresearch.com, wcalhoun@dekaresearch.com
Date Prepared	April 1, 2025

Proposed Device(s)

Trade/Proprietary Name:	twiist system
Classification Name:	Alternate Controller Enabled Insulin Infusion Pump
Device Classification:	880.5730
Product Code:	QFG
Class:	II
Device Panel:	Clinical Chemistry

Predicate Device

The predicate device is the DEKA ACE Pump System, cleared under premarket notification K233952 on March 13, 2024.

The predicate device has not been subject to a design-related recall.

Device Description

The twiist system described herein contains a modification of the labeling of the previously cleared DEKA ACE Pump System (K233952) to add the ConvaTec contact™ detach 23" subcutaneous infusion set and the ConvaTec inset™ 23" and 32" subcutaneous infusions sets as compatible for use with the twiist system.

The twiist system is a wearable alternate controller enabled (ACE) insulin infusion pump 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 twiist system is intended for the management of diabetes mellitus in persons six years of age and greater.

The twiist system was previously cleared and indicated for use with other FDA-cleared subcutaneous infusion sets. This Special 510(k) utilizes the same test methodology and acceptance criteria used in its previous clearance to demonstrate compatibility with the additional infusion sets described in this submission. No changes to the hardware or software of the system from that of the predicate are necessary to add the ConvaTec contact detach and ConvaTec inset infusion set compatibility claims.

The twiist system, consistent with the predicate K233952, consists of the following durable and disposable components:

1. **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.
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 a pump and off-the-shelf infusion sets.
3. **Sequel twiist App**: An iOS mobile application that serves as the primary user interface for the system. The twiist app can be downloaded onto the user's personal iPhone.

Indications for Use

The twiist 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 twiist system 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 tables below includes a matrix of the intended use between the subject device and the predicate device.

Characteristic	Predicate Device (K233952)	Subject Device	Substantial Equivalence
Device Classification Regulation and Product Code	Class II Alternate controller enabled insulin infusion pump 21 CFR 880.5730 Product Code: QFG	Class II Alternate controller enabled insulin infusion pump 21 CFR 880.5730 Product Code: QFG	No change
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 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 twiist 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 twiist system 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.	Device name updated. No other changes to indications for use.
Prescription Use	Yes	Yes	No Change
Intended Population	Persons with Diabetes Mellitus ages 6 and above	Persons with Diabetes Mellitus ages 6 and above	No Change
Environment of Use	In professional healthcare facilities and home healthcare environments	In professional healthcare facilities and home healthcare environments	No Change

The intended use and indications for use remain unchanged in the subject device with respect to the predicate device (K233952).

Technological Characteristic Comparison

The table below compares the technological characteristics of the subject device with those of the predicate device.

Characteristic	Predicate Device (K233952)	Subject Device	Equivalence
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
Insulin Bolus Delivery Range	Programmable from 0.05 - 25.00 Units in 0.01 Unit increments.	Programmable from 0.05 - 25.00 Units in 0.01 Unit increments.	Same
Basal Accuracy	Unchanged from K233952	Unchanged from K233952	Same
Bolus Accuracy	Unchanged from K233952	Unchanged from K233952	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/h); 6 hours (Basal, 0.1 U/hr)	10 min (Bolus); 3 hours (Basal, 1 U/h); 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 60601-1-10 • IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • 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 14971	Same
Power Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	Same
Pump Storage Conditions	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity 15% to 90%	Temperatures of -25 °C (-13 °F) to 70 °C (158 °F) Non-condensing humidity 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, audible, and vibratory	Visual, audio, and vibratory	Same

Characteristic	Predicate Device (K233952)	Subject Device	Equivalence
Battery Operating Time	72 hours	72 hours	Same
Compatible Insulins	Humalog U-100 Novolog U-100	Humalog U-100 Novolog U-100	Same
Infusion Set	• Medtronic MiniMed Quick-set Infusion Set: o 43 inch MMT-390 o 42 inch MMT-391 o 23 inch MMT-392 o 23 inch MMT-393 • Medtronic MiniMed Silhouette Infusion Set: o 23 inch MMT-373 • Unomedical Comfort™: o 23 inch • Smiths Medical Cleo 90 Infusion Set: o 24 inch 21-7220-24 o 31 inch 21-7221-24 o 42 inch 21-7222-24 o 24 inch 21-7230-24 o 31 inch 21-7231-24 o 42 inch 21-7232-24	• Medtronic MiniMed Quick-set Infusion Set: o 43 inch MMT-390 o 42 inch MMT-391 o 23 inch MMT-392 o 23 inch MMT-393 • Medtronic MiniMed Silhouette Infusion Set: o 23 inch MMT-373 • Unomedical Comfort™: o 23 inch • Smiths Medical Cleo 90 Infusion Set: o 24 inch 21-7220-24 o 31 inch 21-7221-24 o 42 inch 21-7222-24 o 24 inch 21-7230-24 o 31 inch 21-7231-24 o 42 inch 21-7232-24 • **ConvaTec contact detach Infusion Set:** o **23 inch (FG000016-03)** • **ConvaTec inset Infusion Set:** o **23 inch (FG000016-01)** o **32 inch (FG000016-05)**	Equivalent The subject device has additional compatible infusion sets. The ConvaTec contact detach and inset infusion sets have similar physical characteristics to the other infusion sets currently included on the device label. Performance testing with the added ConvaTec infusion sets demonstrates that subject device performance is equivalent to the predicate device. The methods and acceptance criteria used in this testing are well established in the previous clearance (K233952).

Animal, Clinical, and Bench Data

Bench performance testing was conducted to qualify the additional infusion sets for use with the subject device, and to establish substantial equivalence to the predicate device in terms of safety and effectiveness.

No animal or clinical data were obtained in support of this premarket submission.

Design Control

The twiist system 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 13485:2016.

Conclusion

The differences between the predicate and the subject device do not raise different questions of safety or effectiveness. The twiist system is substantially equivalent to the predicate DEKA ACE Pump System, cleared under premarket notification K233952.