June 17, 2026

Deka Research and Development
Paul Smolenski
Director of Regulatory Affairs
340 Commercial St.
Manchester, New Hampshire 03101

Re: K261672
Trade/Device Name: twiist Automated Insulin Delivery (AID) System
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate controller enabled infusion pump
Regulatory Class: Class II
Product Code: QFG, NDC
Dated: May 20, 2026
Received: May 21, 2026

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 and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	
Please provide the device trade name(s).	

twiist Automated Insulin Delivery (AID) System

Please provide your Indications for Use below.

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 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 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

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), Jessica Smith (alternate) Regulatory Affairs Phone: (603) 669-5139 Fax: (603) 624-0573 psmolenski@dekaresearch.com, jesmith@dekaresearch.com
Date Prepared	May 20, 2026

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 twiist AID System, cleared under premarket notification K250930 on April 2, 2025.

Device Description

The twiist Automated Insulin Delivery (AID) System described herein adds an Android OS compatible version of the twiist App to the previously cleared twiist AID System, K250930.

The twiist AID 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 AID System is intended for the management of diabetes mellitus in persons six years of age and greater.

This Special 510(k) utilizes previously validated test methods and acceptance criteria, with minor, non-impacting modifications to address functionality with the Android OS twiist App described in this submission. No changes to the pump hardware or iAGC software from that of the predicate were made to incorporate the Android OS twiist App.

The twiist system, consistent with the predicate K250930, consists of the following durable and disposable components:

1. **Pump**: A durable pump that incorporates an embedded iAGC and fluid delivery algorithms when interfaced 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 volume measurement chamber. The cassette interfaces to the pump and off-the-shelf infusion sets.
3. **twiist App**: A mobile application that serves as the primary user interface for the system. The twiist app can be downloaded onto the user's personal iOS or Android mobile device.

Since the clearance of K250930, additional minor modifications were made and are detailed in *Device Description_twiist AID System Device Description.pdf*. 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 twiist AID System cleared on April 02, 2025 under K250930. As described throughout this submission, the subject twiist AID System meets the product definition and all of the Special Controls defined in 21 CFR 880.5730 for Alternate Controller Enabled Insulin Infusion Pumps, Product Code QFG.

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 (K250930)	Subject Device	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 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.	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.	No Change
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 (K250930).

Technological Characteristic Comparison

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

Characteristic	Predicate Device (K250930)	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.	No Change
Insulin Basal Rate Delivery Range	0 units/hour - 30 units/hour	0 units/hour - 30 units/hour	No Change
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.	No Change
Basal Accuracy	± 5% at 1 U/hr when measured per IEC 60601-2-24.	Unchanged from K250930.	No Change
Bolus Accuracy	± 20% at 0.05 U boluses and ± 5% at 25 U boluses when measured per IEC 60601-2-24.	Unchanged from K250930.	No Change
Bolus Volume after Occlusion Release	No more than 0.74 units.	No more than 0.74 units.	No Change
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)	No Change
Material Biocompatibility	Compliant with ISO-10993	Compliant with ISO-10993	No Change
Cartridge/Cassette Shelf Life	1 year	1 year	No Change
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.	IP24, indicating protection from solid object larger than 12.5 mm. The pump can tolerate splashing water from any direction for 10 minutes.	Substantially Equivalent. An IP24 rating is adequate for home use. This difference does not raise new questions of safety or efficacy. The subject device product labeling has been updated to reflect the new ingress protection rating.
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	No Change
Power Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	No Change

Characteristic	Predicate Device (K250930)	Subject Device	Equivalence
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%	No Change
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%	No Change
System User Feedback	Visual, audible, and vibratory	Visual, audio, and vibratory	No Change
App Operating System	Apple iOS	Apple iOS, and Android OS	Substantially Equivalent. The Subject device provides an Android OS supported version of the twiist App for use with the pump. The text and format of information displayed to the user, as well as workflows and required user input remains unchanged. The Android OS provides equivalent cybersecurity protections as the predicate iOS system. No additional risks have been introduced.
Battery Operating Time	72 hours	72 hours	No Change
Battery Service Life	4 months	12 months	Substantially Equivalent. The battery has been verified to provide the same performance at the 12-month service life as was initially cleared at the 4-month service life in K213536.
Compatible Insulins	Humalog U-100 Novolog U-100	Humalog U-100 Novolog U-100	No Change

Characteristic	Predicate Device (K250930)	Subject Device	Equivalence
Infusion Set	• Medtronic MiniMed Quick-set Infusion Set: ○ 43 inch MMT-390 ○ 42 inch MMT-391 ○ 23 inch MMT-392 ○ 23 inch MMT-393 • Medtronic MiniMed Silhouette Infusion Set: ○ 23 inch MMT-373 • Unomedical Comfort™: ○ 23 inch • Smiths Medical Cleo 90 Infusion Set: ○ 24 inch 21-7220-24 ○ 31 inch 21-7221-24 ○ 42 inch 21-7222-24 ○ 24 inch 21-7230-24 ○ 31 inch 21-7231-24 ○ 42 inch 21-7232-24 • ConvaTec contact detach Infusion Set: ○ 23 inch (FG000016-03) • ConvaTec inset Infusion Set: ○ 23 inch (FG000016-01) ○ 32 inch (FG000016-05)	• Medtronic MiniMed Quick-set Infusion Set: ○ 43 inch MMT-390 ○ 42 inch MMT-391 ○ 23 inch MMT-392 ○ 23 inch MMT-393 • Medtronic MiniMed Silhouette Infusion Set: ○ 23 inch MMT-373 • Unomedical Comfort™: ○ 23 inch • Smiths Medical Cleo 90 Infusion Set: ○ 24 inch 21-7220-24 ○ 31 inch 21-7221-24 ○ 42 inch 21-7222-24 ○ 24 inch 21-7230-24 ○ 31 inch 21-7231-24 ○ 42 inch 21-7232-24 • ConvaTec contact detach Infusion Set: ○ 23 inch (FG000016-03) • ConvaTec inset Infusion Set: ○ 23 inch (FG000016-01) ○ 32 inch (FG000016-05)	No Change

The technological characteristics of the subject device are substantially equivalent to those of the predicate device.

Animal, Clinical, and Bench Data

Bench performance testing was conducted to verify support for Android OS mobile devices 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 subject twiist system is substantially equivalent to the predicate twiist System, cleared under premarket notification K250930.