March 12, 2026

Medtronic Minimed, Inc.
Omar Becerra
Principal Regulatory Affairs Specialist
18000 Devonshire St.
Northridge, California 91325

Re: K253743
Trade/Device Name: MiniMed Flex pump
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: November 21, 2025
Received: November 24, 2025

Dear Omar Becerra:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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); 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 Management System Regulation (QMSR) (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.

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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
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Enclosure

510(K) Summary
MiniMed Flex Pump

510(k) Submitter and Device Information

Submitter's Name and Address	Medtronic MiniMed, Inc. 18000 Devonshire St Northridge, CA 91325 USA
Primary Contact Person	Omar Becerra Principal Regulatory Affairs Specialist Medtronic MiniMed Inc. Omar.Becerra@medtronic.com
Alternate Contact Person	Siddhi Rasam Sr Manager, Regulatory Affairs Medtronic MiniMed Inc. Siddhi.Rasam@medtronic.com
Device Trade Name	MiniMed Flex Pump
Device Common Name	Alternate Controller Enabled Insulin Infusion Pump (ACE Pump)
Device Classification Name	Alternate Controller Enabled (ACE) Insulin Infusion Pump
Regulation Number	21 CFR 880.5730
Product Codes	QFG
Device Panel	Clinical Chemistry
Device Class	Class II
Predicate Device	K251032 - MiniMed 780G Flex Pump with Interoperable Technology

Device Description

The MiniMed Flex pump is an alternate controller enabled (ACE) pump intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. It can reliably and securely communicate with compatible digitally connected devices, including an integrated continuous glucose monitor (iCGM), interoperable Medtronic continuous glucose monitor (CGM), and interoperable automated glycemic controller (iAGC). The MiniMed Flex pump is intended to be used in conjunction with compatible, digitally connected medical devices (i.e., iAGC and CGM) for the purpose of drug delivery. The MiniMed Flex pump is provided with compatible iAGCs installed, refer to the compatible iAGCs for indications related to iAGC use with MiniMed Flex pump.

The MiniMed Flex pump is an ambulatory, battery-operated, rate-programmable micro-infusion pump. It is a screenless, tubed pump that houses electronics, a pumping mechanism, and a

medication reservoir within the same physical device. It is intended for use with compatible insulin reservoir and insulin infusion set for delivery of basal and bolus insulin according to settings selected or inputs entered by the user or compatible iAGC software based on healthcare provider recommendations.

The MiniMed Flex pump is an interoperable device that communicates via a Bluetooth Low Energy (BLE) wireless electronic interface with digitally connected devices. The MiniMed Flex pump is able to integrate the compatible MiniMed iAGC algorithms into the pump firmware to receive, execute, and confirm commands from an iAGC to adjust delivery of insulin. The pump receives sensor glucose (SG) data from a compatible iCGM or a compatible interoperable Medtronic CGM via BLE and transmits the SG and other CGM data to the iAGCs.

The MiniMed Flex pump is a screenless pump with minimal user interface and manual control capabilities available from the pump itself. The primary user interface and primary display for the MiniMed Flex pump is the MiniMed app, also the user interface for the compatible MiniMed iAGCs, which runs on a compatible iOS or Android device.

Indications for Use / Intended Use

The MiniMed Flex 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 MiniMed Flex 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 MiniMed Flex pump is indicated for use in persons 7 years of age and older.

The MiniMed Flex pump is intended for single patient use and requires a prescription.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The table below provides a side-by-side comparison of the subject device, MiniMed Flex pump compared to its predicate device, MiniMed 780G insulin pump.

Table 1: Technological Characteristics Comparison between MiniMed Flex pump (Subject Device) and MiniMed 780G insulin pump (Predicate Device, cleared in K251032)

	Predicate Device (K251032) MiniMed 780G insulin pump	Subject Device (K253743) MiniMed Flex pump
Device Classification	Alternate Controller Enabled (ACE) Insulin Infusion Pump,	**SAME**
Product Code	QFG	**SAME**
Device Type/Regulation	21 CFR 880.5730	**SAME**
Indications for Use/Intended Use	The MiniMed 780G insulin 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 MiniMed 780G insulin 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 MiniMed 780G insulin pump contains a bolus calculator that calculates an insulin dose based on user-entered data. The MiniMed 780G insulin pump is indicated for use in individuals 7 years of age and older. The MiniMed 780G insulin pump is intended for single patient use and requires a prescription.	The MiniMed Flex 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 MiniMed Flex 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 MiniMed Flex pump is indicated for use in individuals 7 years of age and older. The MiniMed Flex pump is intended for single patient use and requires a prescription.
Prescription Use	Prescription is required	**SAME**
Environment of Use	Professional healthcare facilities and home environments	**SAME**
Patient Environment	On-body wearable ambulatory pump	**SAME**
Intended Population	Persons with diabetes mellitus ages 7 and up	**SAME**
Technological Characteristics	The MiniMed 780G insulin pump is an ambulatory, battery-operated, rate-programmable micro-infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The device houses electronics, a pumping mechanism, a user interface, and a medication reservoir to deliver patient-programmed basal	The MiniMed Flex pump is a screenless ambulatory, battery-operated, rate-programmable micro-infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The device houses electronics, a pumping mechanism, and a medication reservoir to deliver patient-programmed basal rates and

	Predicate Device (K251032) MiniMed 780G insulin pump	Subject Device (K253743) MiniMed Flex pump
	rates and boluses through an infusion set into the subcutaneous tissue.	boluses through an infusion set into the subcutaneous tissue.
Specific Drug/Biological Use	U-100 insulin[1]: Novolog® Humalog® Admelog®	U-100 insulin: Novolog® Humalog® Admelog® Fiasp® Lyumjev®
Principles of Operation	Delivery of insulin (Bolus and Basal) programmed by the patient or compatible iAGC software based on healthcare provider recommendations.	**SAME**
Pump Operating Modes	Manual Mode SmartGuard Mode	**SAME**
Pump Device Accessories	MiniMed Mobile App Compatible FDA cleared infusion sets Compatible FDA cleared reservoirs Belt Clip Pump Covers/Cases	MiniMed Flex Charger Compatible FDA cleared infusion sets Compatible FDA cleared reservoirs Belt Clip Pump Covers/Sleeves
Compatible Interoperable Devices	Integrated Continuous Glucose Monitors (iCGMs) Interoperable Automated Glycemic Controllers (iAGCs) Compatible Interoperable Medtronic Continuous Glucose Monitors (CGMs)	**SAME**
Compatible Connected Devices	N/A	MiniMed App (installed on compatible smartphone or App Manager)
Communication with Compatible Devices	Bluetooth Low Energy (BLE)	**SAME**
Battery Type/ Power Requirements	The MiniMed 780G pump requires an internal lithium-ion rechargeable battery plus one AA (1.5V) battery	The MiniMed Flex pump includes an internal lithium-ion rechargeable battery.
Pump Screen/Controls	Liquid Crystal Display (LCD) Screen + Keypad	The Flex pump is a screenless device. Users receive safety critical alerts from the pump's lights and speaker. The user has limited interaction with the pump through two buttons (the action button and the acknowledge button) and the status light. Alerts are communicated to the MiniMed app where notifications are presented for the user to review and acknowledge.

[1] MiniMed 780G pump use with Fiasp and Lyumjev was cleared in K253470.

	Predicate Device (K251032) MiniMed 780G insulin pump	Subject Device (K253743) MiniMed Flex pump
Wireless control of bolus insulin therapy	The MiniMed 780G insulin pump does not have the capability to allow users to wirelessly interact with insulin therapy via a mobile app.	The MiniMed Flex pump does have the capability to allow users to wirelessly interact with insulin therapy via the MiniMed app.
Predetermined changed control plan (PCCP)	The MiniMed 780G insulin pump was cleared with an authorized PCCP that included modifications for integrating with potential additional commercialized interoperable devices in the future.	**SAME**

Summary of Non-Clinical Performance Data

Medtronic MiniMed conducted extensive performance bench testing for MiniMed Flex pump to demonstrate substantial equivalence to the predicate device and to ensure that the subject device meets all applicable ACE Special Controls requirements defined in 21 CFR 880.5730. These are summarized below:

Special Controls:

Evaluation and adherence to the Special Controls of the Predicate Device (K251032) demonstrates continued assurance of the safety and effectiveness of the Subject Device

Delivery Volume Accuracy

Delivery volume accuracy (DVA) testing for the MiniMed Flex pump was conducted to assess the delivery volume accuracy performance of the pump for foreseeable use conditions as required by the ACE special controls requirements stated in 21 CFR 880.5730(b). The test results support that the device is safe to use under foreseeable use conditions and expected environments.

Catheter Occlusion Detection

Catheter Occlusion Detection testing was conducted with U100 insulins (Humalog, NovoLog, Admelog, Fiasp, and Lyumjev) to demonstrate the incidence of catheter blockage due to insulin crystallization. The test results showed there were no drug-fluid-path occlusions and were confirmed to be acceptable.

Drug Stability and Compatibility

Drug stability and compatibility testing was performed with U100 insulins (Humalog, NovoLog, Admelog, Fiasp, and Lyumjev) used with the reservoir and infusion sets compatible to MiniMed Flex pump. The test results demonstrated that the compatible

reservoir and infusion sets do not adversely affect the insulins being delivered, and that the insulin types do not adversely affect the pump.

Software Verification and Validation

Software verification activities were performed in accordance with ISO 14971:2019 "*Medical Devices - Application of Risk Management to Medical Devices*," IEC 62304:2006/A1:2016, "*Medical Device Software - Software Life Cycle Processes*," and FDA guidance "*Content of Premarket Submissions for Device Software Functions*" (June 2023).

Additionally, cybersecurity activities were all completed per cybersecurity plan and cybersecurity risks were assessed for impact to confidentiality, integrity, and availability. A robust cybersecurity risk assessment was conducted, all cybersecurity risks with potential to impact safety were mitigated.

Interoperability

Interoperability documentation was provided in accordance with FDA Guidance *"Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices"* (September 2017) and the requirements defined by the ACE special controls 21 CFR 880.5730(b)(3)-(5).

Human Factors Validation

A human factors and usability engineering process was performed on MiniMed Flex pump with compatible Medtronic CGMs and compatible MiniMed iAGCs in accordance with IEC 62366-1:2015, HE75:2009 and FDA's guidance document, "*Applying Human Factors and Usability Engineering to Medical Devices"* (February 2016). Results of the human factors validation testing demonstrated that the device is safe and effective for the intended users, intended uses and expected tasks, and intended use environments.

Labeling

The MiniMed Flex pump labeling for users and healthcare practitioners is sufficient and satisfies applicable requirements of 21 CFR 801.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and EMC testing were conducted on MiniMed Flex pump in accordance with IEC 60601-1, IEC 60601-1-2, collateral standards of IEC 60601-1, and additional standards as applicable.

Pre-determined Change Control Plan (PCCP)

A Pre-determined change control plan (PCCP) for planned modifications to the MiniMed Flex Pump, was provided in accordance with the FDA *Draft* Guidance, *"Predetermined Change Control Plans* for *Medical Devices"* (August 2024). It included modifications for integrating with potential additionchal commercialized interoperable devices in the future. The PCCP included a description of modifications, a modification protocol, traceability from modifications to the modification protocols and an impact assessment.

Conclusion

The MiniMed Flex pump has the same intended use and indications as the Predicate Device, MiniMed 780G insulin pump, cleared in K251032. The required technical documentation provided in this 510(k) demonstrates the MiniMed Flex pump is as safe and effective as the Predicate Device. Furthermore, the subject device meets all the Special Controls requirements for Alternate controller enabled infusion pump defined in 21 CFR 880.5730. Therefore, the MiniMed Flex pump has been evaluated to be substantially equivalent to the Predicate Device and does not raise new or different questions of safety or effectiveness.