September 16, 2026

CamDiab
% Nima Akhlaghi
Director, Digital Health Regulatory Affairs
MCRA, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K261896
Trade/Device Name: iOS CamAPS FX
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable automated glycemic controller
Regulatory Class: Class II
Product Code: QJI
Dated: July 24, 2026
Received: July 24, 2026

Dear Nima Akhlaghi:

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 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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261896

Device Name
CamAPS FX

Indications for Use *(Describe)*
CamAPS FX is a mobile app intended for managing glucose levels in people with type 1 diabetes, aged 2 years and over, using a hybrid closed loop approach (automated basal insulin delivery with manual bolusing for meals). Additional age and other restrictions may apply depending on the chosen continuous glucose monitor and insulin pump.

CamAPS FX requires an insulin pump and a continuous glucose monitor (CGM) to fulfill its intended use. The list of supported insulin pumps and CGMs is provided in this User Manual.

CamAPS FX is indicated for use in pregnancy complicated by type 1 diabetes provided that linked continuous glucose monitoring system is approved for use in pregnancy.

CamAPS FX is for prescription use only.

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

Basic.Information

Manufacturer: CamDiab Ltd.
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Preparation Date: August 24, 2026

Subject Device trade name: CamAPS FX (iOS)

Medical Specialty: Clinical Chemistry

Classification: 21 CFR 862.1356

Regulation Name: Interoperable automated glycemic controller

Class: II

Product Code: QJI

Predicate Device Trade Name: CamAPS FX

Medical Specialty: Clinical Chemistry

Classification: 21 CFR 862.1356

Regulation Name: Interoperable automated glycemic controller

Class: II

Product Code: QJI

Indications.for.use
CamAPS FX is a mobile app intended for managing glucose levels in people with type 1 diabetes, aged 2 years and over, using a hybrid closed loop approach (automated basal insulin delivery with manual bolusing for meals). Additional age and other restrictions may apply depending on the chosen continuous glucose monitor and insulin pump.

CamAPS FX requires an insulin pump and a continuous glucose monitor (CGM) to fulfil its intended use. The list of supported insulin pumps and CGMs is provided in the User Manual.

CamAPS FX is indicated for use in pregnancy complicated by type 1 diabetes provided that the linked continuous glucose monitoring system is suitable for use in pregnancy.

CamAPS FX is for prescription use only.

Device.description
For this specific application CamAPS FX is an iOS App intended to receive blood glucose readings from an iCGM device to control an insulin pump. The 'FX' variant of the App has been evaluated in individuals aged 2 years and older including pregnant women. The App adopts a modular design. It comprises software items including Main Platform and Control Algorithm. The former manages data, implements user interface, bolus calculator, cloud upload connectivity, alert/alarm management, and other pertinent aspects. The latter implements an adaptive model-predictive control algorithm which processes sensor glucose data and generates advice on insulin dosing. Control Algorithm embeds an advanced model of insulin pharmacokinetics and pharmacodynamics and personalizes insulin delivery to a particular individual based on processing data collected during the operation of the App.

Additional software items include insulin pump and CGM libraries. These software items implement secure wireless (Bluetooth or Low Energy Bluetooth) communication with insulin pumps and CGM transmitters. Insulin pump and CGM devices are manufactured by third parties and are not part of the App. The App has been designed to allow additional insulin pumps and CGM systems to be added to the App as they are cleared for use in the US market.

Table 1: Comparison of CamAPS FX (iOS) with CamAPS FX (Android) (**K232603**).

	CamAPS FX iOS (subject device)	**CamAPS FX Android (K232603)**	**Justification for differences**
Product Code	QJI	QJI	Same
Regulation Name	21 CFR 862.1356, Interoperable Automated Glycemic Controller	21 CFR 862.1356, Interoperable Automated Glycemic Controller	Same
Indications for Use	CamAPS FX (iOS) is a mobile app intended for managing glucose levels in people with type 1 diabetes, aged 2 year and over, using a hybrid closed loop approach (automated basal insulin delivery with manual bolusing for meals). Additional age restrictions may apply depending on the chosen continuous glucose monitor and insulin pump. CamAPS FX requires an insulin pump and a continuous glucose monitor (CGM) to fulfil its intended use. The list of supported insulin pumps and CGMs is provided in this User Manual. CamAPS FX is intended for use with rapid or ultra-rapid insulin analogues including diluted analogues.	CamAPS FX is an Android app intended for managing glucose levels in people with type 1 diabetes, aged 2 year and over, using a hybrid closed loop approach (automated basal insulin delivery with manual bolusing for meals). Additional age restrictions may apply depending on the chosen continuous glucose monitor and insulin pump. CamAPS FX requires an insulin pump and a continuous glucose monitor (CGM) to fulfil its intended use. The list of supported insulin pumps and CGMs is provided in this User Manual. CamAPS FX is intended for use with rapid or ultra-rapid insulin analogues including diluted analogues.	The word android has been replaced with the word mobile

Target Patient Population	Type 1 diabetes mellitus in persons 2 year of age and greater.	Type 1 diabetes mellitus in persons 2 year of age and greater.	Same
Principal Operator	CamAPS FX predicts glucose levels up to 4 hours in the future based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and activity) and uses that prediction to adjust insulin delivery. CamAPS FX can be used to adjust insulin delivery every 8-10 minutes based on actual and predicted CGM sensor readings. Users must manually deliver meal boluses they can calculate using a bolus application function within CamAPS FX. that shall work as per application associated with the ACE Pump. The Users can manually deliver correction boluses when CamAPS is active.	CamAPS FX predicts glucose levels up to 4 hours in the future based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and activity) and uses that prediction to adjust insulin delivery. CamAPS FX can be used to adjust insulin delivery every 8-10 minutes based on actual and predicted CGM sensor readings. Users must manually deliver meal boluses they can calculate using a bolus application function within CamAPS FX. that shall work as per application associated with the ACE Pump. The Users can manually deliver correction boluses when CamAPS is active.	Same
Use Location	At Home	At Home	Same
Number of Users	Single user only	Single user only	Same
Principle of Operation	CamAPS FX predicts glucose levels up to 4 hours in the future	CamAPS FX predicts glucose levels up to 4 hours in the future	Same

	based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and activity) and uses that prediction to adjust insulin delivery. CamAPS FX can be used to adjust insulin delivery every 8-10 minutes based on actual and predicted CGM sensor readings. Users must manually deliver meal boluses they can calculate using a bolus application function within CamAPS FX. that shall work as per application associated with the ACE Pump. The Users can manually deliver correction boluses when CamAPS is active.	based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and activity) and uses that prediction to adjust insulin delivery. CamAPS FX can be used to adjust insulin delivery every 8-10 minutes based on actual and predicted CGM sensor readings. Users must manually deliver meal boluses they can calculate using a bolus application function within CamAPS FX. that shall work as per application associated with the ACE Pump. The Users can manually deliver correction boluses when CamAPS is active.	
Type of Algorithm	Hybrid Closed Loop – Multi model adaptive predictive control	Hybrid Closed Loop – Multi model adaptive 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 as per APCam-FX- D602 ACE Pump Interoperability	An ACE pump that has the specifications and meets the pre-specified acceptance criteria as per APCam-FX- D602 ACE Pump Interoperability Requirements	Same

	Requirements		
Device Design or Material	CamAPS FX is a mobile application and a Software as Medical Device (SaMD) installed on a host mobile device	CamAPS FX is a mobile application and a Software as Medical Device (SaMD) installed on a host mobile device	Same
Algorithm Platform	iPhone	Android Smart Phone	Equivalent configuration for calculations of algorithm
User Experience Platform	iPhone	Android Smart Phone	Compatible iPhone as opposed to Compatible Android Phone
Insulin Compatibility	Novolog, Humalog, Fiasp, or Lyumjev U-100	Novolog, Humalog, Fiasp, or Lyumjev U-100	Same
User-controlled Target Range Settings	Target range during automode 80-200mg/dL Target range for correction boluses: as per ACE pump specification	Target range during automode 80-200mg/dL Target range for correction boluses: as per ACE pump specification	Same
Auto-populating bolus recommendation based on iCGM value: **In closed loop mode** **In open loop mode**	 No Yes	 No Yes	Same
Data List & 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
Bench Performance	CamAPS FX (iOS) performance was verified and validated through software verification testing including special controls, cybersecurity, wireless, and connected devices compatibility testing.	CamAPS FX performance was verified and validated through software verification testing including special controls, cybersecurity, wireless, and connected devices compatibility testing.	Same, although separate testing plans/reports
Clinical Performance	CamAPS FX Clinical Performance is supported by a number of randomized Clinical Studies in children as young as 2 year old, older children, adolescents, adults, older adults and pregnant women. Real world assessment was also conducted across EU and Australia.	CamAPS FX Clinical Performance is supported by a number of randomized Clinical Studies in children as young as 2 year old, older children, adolescents, adults, older adults and pregnant women. Real world assessment was also conducted across EU and Australia.	Same data sets
Patient Preference	CamDiab conducts annual user surveys.	CamDiab conducts annual user surveys.	Same
Risk Assessment	CamAPS FX performed Risk Assessment including detailed hazard analysis based on ISO 14971.	CamAPS FX performed Risk Assessment including detailed hazard analysis based on ISO 14971.	Same risk file

Training	CamAPS FX includes mandatory in-app learning and setup (user training) before the user can use CamAPS FX.	CamAPS FX includes mandatory in-app learning and setup (user training) before the user can use CamAPS FX.	Same
User Guide	CamAPS FX electronic User Guide also includes all special controls, clinical performance information and other information needed per cybersecurity and interoperability requirements.	CamAPS FX electronic User Guide also includes all special controls, clinical performance information and other information needed per cybersecurity and interoperability requirements.	Same

CamDiab acknowledges that expanding the application to an additional operating system represents a significant change and therefore requires submission of a new 510(k). This determination is consistent with CamDiab internal procedure P-606 Regulatory Filing Determination for FDA-003.

The purpose of this plan (see Predetermined Change Control Plan (PCCP) section below) is to define the processes CamDiab will follow when assessing and executing the porting of the application to iOS. This document describes the protocol to be followed, with the expectation that, if cleared by the Agency, no additional marketing submission or regulatory correspondence will be required to release the iOS version to the market.

All other modifications to the CamAPS FX application are outside the scope of this process and will be evaluated in accordance with Figure 1 of the FDA guidance 'Deciding when to Submit a 510(k) for a software change to an existing device' and/or 'Deciding When to Submit a 510(k) for a Change to an Exising Device'. Any modification to the CamAPS FX application will be performed in compliance with CamDiabs accredited Quality System as described in document P-001, Quality Manual.

Performance. Testing

No additional performance testing was performed for this device. Software Verification and validation were performed to demonstrate equivalent performance to the predicate following the update to operating system compatibility.

Predetermined Change Control Plan (PCCP)

This submission includes a Predetermined Change Control Plan (PCCP) detailing the proposed device modifications. The PCCP outlines the nature of these planned changes and provides a modification protocol to guide the testing, verification, validation, and implementation processes, ensuring the device continues to meet substantial equivalence. This PCCP is a modification of the original PCCP included within K232603 adding a Planned Modification for addition of Addition of Supported Mobile Operating Systems.

The planned modifications described in the PCCP are summarized in the table 2 below.

The table below describes each of the proposed modifications and describes how it will be tested to ensure substantial equivalence of the device after the modification.

Table 2: The planned modifications described in CamDiab PCCP APCam-FX-D36-RevE-US Predetermined Change Control Plan

Planned Modifications	**Description**	**Testing Method and Communication to Users, as needed.**
1. Addition of Supported Mobile Operating Systems	CamDiab intends to expand the availability of the CamAPS FX application to iOS while maintaining the same intended use, principles of operation, therapeutic functionality and clinical	Verified and validated by the requirements of the Modification Protocol, including necessary regression testing. Users will be notified of

	performance as the currently FDA-authorized implementation.	software updates (including any user instructions for the update process) in accordance with the authorized PCCP. Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's upgraded operating system.
2. Addition of compatible Alternate Controller Enabled (ACE) Insulin Pumps	Unchanged from K232603. See previous 510k Summary for details.	Unchanged from K232603. See previous 510k Summary for details.
3. Addition of Compatible Integrated Continuous Glucose Monitoring Systems	Unchanged from K232603. See previous 510k Summary for details.	Unchanged from K232603. See previous 510k Summary for details.

Conclusion

The information submitted in this premarket notification supports the safety and effectiveness of the CamAPS FX (iOS) as compared to the predicate device CamAPS FX (Android) in context of the intended use and labelling of the device.