



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K261896

B Applicant

Camdiab Ltd.

C Proprietary and Established Names

CamAPS FX

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJI	Class II	21 CFR 862.1356 - Interoperable Automated Glycemic Controller	CH - Clinical Chemistry
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary- function value calculator	CH - Clinical Chemistry

E Purpose for Submission:

Predetermined change control plan

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

CamAPS FX is indicated for use with NovoLog and HumaLog U-100 insulin (age 2 years and over and including pregnancy), and Fiasp and Lyumjev U-100 (age 18 and over and excluding pregnancy).

Pregnant users should only utilize the CamAPS FX app with a continuous glucose monitoring system suitable for use during pregnancy. Prior to initiating use of the CamAPS FX app, pregnant users should consult with their healthcare providers.

CamAPS FX should not be used by anyone who is:

- Unable to notice alerts, alarms and reminders because of physical limitations.
- Unable to monitor glucose as recommended by their healthcare provider.
- Unable to maintain contact with their healthcare provider
- Unwilling or unable to follow the instructions for use and intended uses of compatible insulin pumps and continuous glucose monitor devices.

CamAPS FX should not be used in clinical scenarios where the safety and effectiveness of iOS CamAPS FX has not been evaluated, such as inpatient/hospitalized patient use.

III Device Description

CamAPS FX is a mobile app intended to receive glucose readings from an integrated continuous glucose monitoring (iCGM) device to control an insulin pump. 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 Main Platform manages data, implements user interface, bolus calculator, cloud upload connectivity, alert/alarm management, and other pertinent aspects. The Control Algorithm implements an adaptive model-predictive control algorithm which processes sensor glucose data and generates advice on insulin dosing.

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 which meet the sponsor's predetermined specifications to be added to the App after they are cleared for use in the US.

The CamAPS FX App operates in one of the following modes:

- Auto Mode Off (open loop)
 - The pump operates at the pre-programmed basal profile, or as instructed by the user. The communication with the CGM is maintained and the sensor glucose information is displayed.
 - Auto Mode Off is the default mode of operation on system start-up.
- Auto Mode On (closed loop)
 - A mode of operation where insulin delivery is directed by the app replacing pre-programmed basal insulin delivery.
 - Once Auto Mode On is activated by the user, the system will stay in this mode until the user deactivates it.
- Auto Mode “Attempting”
 - A mode of operation when the app is attempting to enter Auto Mode but a condition is preventing it from doing so. The reasons leading to “Attempting” auto mode include:
 - Sensor glucose data unavailable (includes sensor warmup)
 - Loss of communication with insulin pump
 - Pump insulin delivery suspended
 - Total daily insulin dose exceeded
 - Bluetooth turned off (pump or smartphone)
 - Extended bolus disallowed on the pump
 - The ‘Attempting’ mode continues until the condition preventing the start of Auto Mode is resolved. When in ‘Attempting’ mode, insulin infusion will revert to the pre-programmed basal rate after approximately 30 minutes.
- “Fail Safe” Mode
 - In the event of an unrecoverable error or your smart device depowering, your insulin pump will revert to the pre-programmed basal profile within 30 minutes.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

CamAPS FX

B Predicate 510(k) Number(s):

K232603

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K261896</u>	<u>K232603</u>
Device Trade Name	CamAPS FX	CamAPS FX
General Device Characteristic Similarities		

Intended Use/Indications For Use	Mobile app intended for managing glucose levels in people with type 1 diabetes using a hybrid closed loop approach (automated basal insulin delivery with manual bolusing for meals). CamAPS FX requires an insulin pump and a continuous glucose monitor (CGM) to fulfill its intended use.	Same
Device hosting controller	Mobile app	Same
Target patient population	Type 1 diabetes mellitus in persons 2 year of age and greater.	Same
User-controlled target range settings	Target range during auto mode: 80-198 mg/dL	Same
General Device Characteristic Differences		
PCCP	Add compatible ACE pumps Add compatible iCGMs Add compatible iOS operating system	Add compatible ACE pumps Add compatible iCGMs

Predetermined Change Control Plan (PCCP): In addition to the similarities and differences between the candidate and the predicate device listed in the table above, the candidate device has an authorized PCCP for qualifying and integrating new compatible FDA-cleared iCGMs and ACE pumps. While those modifications are unchanged from the PCCP approved in K232603 a new modification was added to the PCCP for the addition of supported iOS mobile operating system. The PCCP includes a description of the modifications, a modification protocol, and an impact assessment. The PCCP specifies the testing methods, validation activities, and performance requirements to implement the specified modifications such that CamAPS FX remains as safe and as effective as the predicate device and continues to comply with 21 CFR 862.1356(b). The sponsor's PCCP comprises the following for each subject iAGC and ACE pump:

- A new candidate iCGM must have demonstrated compatibility to established minimum iCGM performance, compatibility, and sensor specifications before proceeding with qualification. Once a compatible candidate iCGM is identified, the sponsor will conduct virtual clinical trial testing with virtual patients, with pre-defined acceptance criteria based on virtual patient equivalency testing and glycemic outcomes from the iAGC clinical study. Software design integration of the new iCGM with the subject iAGC will

then be completed, and integration V&V testing will be conducted according to the established PCCP. If integration V&V testing meets the PCCP's prespecified acceptance criteria, the iCGM may be added as an interoperable component to the subject iAGC

- A new candidate ACE pump must have demonstrated compatibility to established minimum ACE pump compatibility and performance specifications defined in the PCCP before proceeding to software design integration with the subject iAGC. Integration V&V testing will then be conducted according to the established PCCP. If integration V&V testing meets the PCCP's prespecified acceptance criteria, the ACE pump may be added as an interoperable component to the subject iAGC.
- Related iAGC labeling will be revised as needed to identify new qualified and integrated compatible devices or to remove previously compatible devices found to no longer be compatible. Communication will be provided through various channels to notify users about a new compatible device or previously compatible but now incompatible device.

New in this PCCP the sponsor proposes users will be notified of software updates (including any user instructions for the update process) and labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's upgraded operating system compatibility.

V Standards/Guidance Documents Referenced:

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes. Recognition Number: 13-79
- IEC 62366-1:2015 Medical Devices - Application of usability engineering to medical devices. Recognition Number: 5-129
- ISO 60601-1-10:2008+A1:2015 Medical electrical equipment- Part 1-10: General requirements for basic safety and essential performance. Recognition Number: 19-37
- ISO 60601-1-11:2015 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical. Recognition Number: 19-47
- ISO 14971:2019 + A1:2021 Medical Devices- Application of risk management to medical devices. Recognition Number: 5-125
- ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice. Recognition Number: 2-282
- AAMI TIR57:2016/(R)2019 Principles for medical device security-Postmarket risk management for device manufacturers. Recognition Number: 13-83

VI Performance Characteristics:

A. Non-Clinical Performance

No new non-clinical studies were performed to support the subject device. Non-Clinical Performance was validated in K232603.

B. Clinical Studies:

No new clinical studies were performed to support the subject device. Clinical performance was validated in K232603. The intended users, intended use, clinical workflow, and core insulin dosing algorithm remain unchanged from the predicate device. Therefore, additional clinical testing was not necessary to demonstrate substantial equivalence.

C. Other Supportive Device Performance Characteristics Data

Predetermined Change Control Plan (PCCP):

A predetermined change control plan (PCCP) for integrating with potential interoperable devices and adding iOS operating system compatibility was provided according to the FDA Guidance “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff.” The PCCP includes a description of modifications, a modification protocol and an impact assessment, and was determined to be adequate to support and clearly specify expectations, requirements, and interface specifications for potential interoperable devices (e.g., iCGMs and ACE pumps). The sponsor has performed software and bench testing to verify and validate that these interface control specifications meet the special controls and their controller’s requirements for performance, communications, and data logging. In addition, the plans provided by the sponsor covered their approach to working with connected device companies regarding contractual issues, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities (e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

The sponsor additionally provided software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices, as well as failsafe design features to mitigate the risks associated with interruption of communication with digitally connected devices. These protocols were executed in the comprehensive software testing performed by the sponsor which included hardware prototype testing and software integration testing.

By design, CamAPS FX can only be used with compatible iCGM and ACE Pump devices with which it has been validated for use. CamAPS FX will not allow use of an unvalidated ACE pump or iCGM. There are controls within the software to prevent use of CamAPS FX in these cases. To support the future integration of compatible ACE pumps and iCGMs with CamAPS FX, the sponsor also provided protocols (“APCam-FX-D36-RevC-US Predetermined Change Control Plan” outlining their validation strategy for determining compatibility of new devices with the CamAPS FX. The protocols included pre-specified procedures, validation strategies, and acceptance criteria for software, cybersecurity, device interoperability, human factors, labeling, and training materials, with the anticipated features and specifications of ACE pumps and iCGMs as these are anticipated changes foreseen at the time of the submission. These protocols, along with the software testing conducted, were found to be adequate to support the robustness of the sponsor’s software test protocols to validate future integration of digitally connected devices that meet the pre-specified specifications and acceptance criteria. CamAPS FX must not be distributed until the pre-specified acceptance criteria in the PCCP are met. FDA has determined that when a modification is made in accordance with “APCam-FX-D36-RevC-US Predetermined Change Control Plan” and the validation strategy described in this 510(k), then the modification would not significantly affect safety or effectiveness of the device and no new 510(k) would be required. Changes made that are inconsistent with the modifications described in “APCam-FX-D36-RevC-US Predetermined Change Control Plan” that were reviewed in this submission could be significant modifications that could significantly affect the safety and/or effectiveness of this device (e.g., such changes could compromise the clinical functionality or

performance specifications that are directly associated with the intended use of the device), in which case a new premarket submission would be required (see 21 CFR 807.81(a)(3)).

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.