510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K232603

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

II Submission/Device Overview:

A Purpose for Submission:

New device.

B Type of Test:

Not applicable.

III 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 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.

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 CamAPS FX has not been evaluated, such as inpatient/hospitalized patient use.

IV Device/System Characteristics:

A Device Description:

CamAPS FX is an Android 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.

B Instrument Description Information:

1. Instrument Name:
   CamAPS FX

2. Specimen Identification:
   N/A

3. Specimen Sampling and Handling:
   N/A

4. Calibration:
   N/A

5. Quality Control:
   N/A

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Tidepool Loop

B Predicate 510(k) Number(s):
K203689

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232603	K203689
Device Trade Name	CamAPS FX	Tidepool Loop
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

General Device Characteristic Differences		
Target patient population	Type 1 diabetes mellitus in persons 2 year of age and greater.	Type 1 diabetes mellitus in persons 6 years of age and greater.
Mobile app platform	Android smart phone	iPhone
User-controlled target range settings	Target range during auto mode: 80-198 mg/dL	Correction Range: 87 - 180 mg/dL Pre-Meal Range: Glucose Safety Limit (which can be set from 67-110 mg/dL) - 130 mg/dL Workout Range: the higher of 85 mg/dL or the Glucose Safety Limit (which can be set from 67-110 mg/dL) - 250 mg/dL

VI Standards/Guidance Documents Referenced:

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not applicable.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Accuracy (Instrument):
   Not applicable.

5. Carry-Over:

   Not applicable.

B Other Supportive Instrument Performance Characteristics Data:

Summary of Clinical Testing:
The CamAPS FX app has been evaluated in a series of randomized clinical studies. Ten key studies (AiDAPT, DAN06, KidsAP02, AP@home04 extension, DAN05, CLOuD, APCam11, FastKids, AP@home04 Phase 3, and AP@home04 Phase 4) were used to support substantial equivalence of the subject device. These studies utilized either the most recent, to-be-marketed version of the CamAPS FX algorithm, 0.3.71, or version 0.3.46, which is functionally identical. All studies were performed outside the United States (OUS) except for APCam11 and Dan05, which enrolled participants in the US.

Baseline Demographics
The majority of studies enrolled current pump users, with the exception of AiDAPT and CLOuD, which enrolled users on multiple daily injections (MDI) users. Subjects already on an insulin pump continued on their existing pump in the control arm or usual care phase of all studies. Similarly, subjects on MDI continued on their existing MDI regimen in the control arm of the AiDAPT and CLOuD studies. All studies included majority White/Caucasian subjects, with the lowest percentage of White participants being 80% in the Fastkids study, and the highest being 100% in the AP@home04 phase 4 study.

Table 1: Baseline characteristics at enrollment

Study (type)	Study Arm	*N*	Study Duration	Age, Mean years ± SD (range)	Sex, % female
AiDAPT (RCT)	Closed loop	61	From <16 weeks gestation to delivery	32±5 (20 to 43)	100
	Control	63	From <16 weeks gestation to delivery	32±6 (20 to 45)	100
DAN06 (Randomized crossover)	Overall	37	2x16 weeks	67±5 (60 to 80)	43
KidsAP02 (Randomized crossover)	Overall	74	2x16 weeks	6±2 (2 to 8)	42
AP@home04 extension (phase 2) (Randomized crossover)	Overall	29	2x4 weeks	41±13 (29 to 62)	52
DAN05 (RCT)	Closed loop	65	6 months	13±3 (8 to 18)	57
	Control	68	6 months	13±3 (6 to 18)	57
CLOuD (RCT)	Closed loop	51	2 years	12±2 (10 to 16)	49
	Control	46	2 years	12±2 (10 to 16)	39
APCam11 (RCT)	Closed loop	46	12 weeks	25±14 (8 to 65)	48
	Control	40	12 weeks	24±14 (6 to 60)	55
FastKids (Randomized crossover)	Overall	25	2x8 weeks	5±1 (2 to 7)	32
AP@home04 – Phase 3 (Randomized crossover)	Overall	25	2x8 weeks	38±9 (24 to 53)	52
AP@home04 – Phase 4 (Randomized crossover)	Overall	28	2x8 weeks	44±11 (23 to 68)	36

N: number of subjects; SD: standard deviation; RCT: randomized controlled trial

Safety Results

The table below summarizes the incidence of severe hypoglycemic and diabetic ketoacidosis events throughout each clinical study. The duration of each study can be found in Table 1 above.

Table 2: Adverse Events by Study Treatment Group in Each Clinical Study

Study	Study Arm/Phase	*N*	Severe Hypoglycemia, # of events	Diabetic Ketoacidosis (DKA), # of events
AiDAPT	Closed loop	61	6	1
	Control	63	5	1
DAN06	Closed loop	36	0	0
	Control	37	2	0
KidsAP02	Closed loop	73	1	0
	Control	74	0	0
AP@home04 extension (phase 2)	Closed loop	29	0	0
	Control	28	0	0
DAN05	Closed loop	65	4	2
	Control	68	3	0
CLOuD	Closed loop	51	5	1
	Control	46	1	0
APCam11	Closed loop	46	0	1
	Control	40	0	0
FastKids	Closed loop with Fiasp	25	0	0
	Closed loop with Novolog	25	0	0
AP@home04 – Phase 3	Closed loop with Fiasp	25	0	0
	Closed loop with Novolog	25	0	0
AP@home04 – Phase 4	Closed loop with Lyumjev	26	0	0
	Closed loop with Humalog	27	0	0

Observed Results
The data below describes how the device performed during the studies.

Table 3: Overall Glycemic Outcomes During the Clinical Studies

Study	Study Arm/Phase (number of subjects)	% time in range 70-180 mg/dL, mean ± SD	% time below 70 mg/dL, Median (IQR)	% time below 54 mg/dL, Median (IQR)	% time above 180 mg/dL, Mean ± SD	Mean Glucose (mg/dL), Mean ± SD
AiDAPT	Closed loop (n=59)	68±11*	2.3** (1.5 to 3.3)	0.7 (0.5 to 1.2)	11±9	125±14
	Control (n=61)	56±13*	2.0** (1.3 to 4.4)	0.7 (0.4 to 1.7)	17±11	136±16
DAN06	Closed loop (n=36)	80±8	1.7 (1.3 to 2.4)	0.2 (0.1 to 0.3)	18±8	141±13
	Control (n=37)	71±13	1.7 (0.9 to 2.7)	0.2 (0.1 to 0.3)	27±14	153±20
KidsAP02	Closed loop (n=73)	72±6	4.9 (3.3 to 6.7)	1.0 (0.6 to 1.4)	23±7	146±12
	Control (n=74)	63±9	4.5 (2.9 to 7.3)	0.9 (0.4 to 1.6)	32±10	158±19
AP@home04 extension (phase 2)	Closed loop (n=29)	76±6	2.9 (2.3 to 40)	0.3 (0.1 to 0.5)	20±6	142±9
	Control (n=28)	66±8	5.3 (3.5 to 10.0)	1.0 (0.5 to 2.6)	27±10	150±16
DAN05†	Closed loop (n=19)	63±9‡	10.8‡ (5.7 to 20.7)	2.9‡ (1.6 to 6.1)	24±8‡	141±18‡
	Control (n=24)	39±13‡	6.3‡ (1.7 to 16.5)	1.4‡ (0.2 to 6.2)	47±17‡	177±38‡
CLOuD	Closed loop (n=42)	64±15‡	8.1‡ (5.0 to 17.2)	2.0‡ (0.4 to 4.7)	22±11‡	142±34‡
	Control (n=30)	49±18‡	4.8‡ (2.7 to 11.7)	1.1‡ (0.1 to 3.4)	42±19‡	176±47‡
APCam11	Closed loop (n=46)	65±8	2.6 (1.9 to 3.6)	0.3 (0.2 to 0.6)	32±8	160±13
	Control (n=40)	54±9	3.9 (1.7 to 5.3)	0.5 (0.2 to 0.9)	42±10	175±18
FastKids	Closed loop Fiasp (n=25)	64±9	3.5 (2.6 to 6.3)	0.8 (0.5 to 1.8)	31±9	160±16
	Closed loop Novolog (n=25)	65±9	3.7 (2.6 to 6.2)	0.8 (0.4 to 1.9)	31±9	160±14

Study	Study Arm/Phase (number of subjects)	% time in range 70-180 mg/dL, mean ± SD	% time below 70 mg/dL, Median (IQR)	% time below 54 mg/dL, Median (IQR)	% time above 180 mg/dL, Mean ± SD	Mean Glucose (mg/dL), Mean ± SD
AP@home04 – Phase 3	Closed loop with Fiasp (n=25)	75±8	2.4 (1.2 to 3.2)	0.4 (0.2 to 0.7)	22± 9	146±14
	Closed loop with Novolog (n=25)	75±8	2.9 (1.7 to 4.0)	0.7 (0.2 to 0.9)	21±9	144±14
AP@home04 – Phase 4	Closed loop with Lyumjev (n=26)	79±10	2.3 (1.3 to 2.7)	0.3 (0.2 to 0.5)	19±10	142±14
	Closed loop with Humalog (n=27)	76±10	2.1 (1.4 to 3.3)	0.3 (0.2 to 0.5)	22±10	146±16

* pregnancy specific time in range 63 to 140 mg/dL
** < 63mg/dL
†when using CamAPS FX
‡measured by multiple CGMs including the Dexcom G6 and the Abbott FreeStyle Libre Pro

Table 4: Available HbA1c Observed During the Clinical Studies

Study	Study Arm/Phase (# of subjects)	Baseline HbA1c (%), Mean ± SD	HbA1c at end of study (%), Mean ± SD
AiDAPT	Closed loop (n=59)	7.6±1.1	6.0±0.5
	Control (n=61)	7.9±1.3	6.4±0.5
DAN06 (cross-over)	Closed loop (n=36)	7.4±0.9	6.7±0.7
	Control (n=37)	7.4±0.9	6.9±0.9
KidsAP02	Closed loop (n=73)	7.3±0.7	6.6±0.6
	Control (n=74)	7.3±0.7	7.0±0.7
AP@home04 extension (phase 2)	Closed loop (n=29)	6.9±0.5	NA
	Control (n=28)	6.9±0.5	NA
DAN05*	Closed loop (n=21)	7.9±0.9	6.8±0.5
	Control (n=24)	8.0±0.6	7.9±0.8
CLOuD	Closed loop (n=47)	10.7±1.8	6.9±1.0
	Control (n=36)	10.5±1.6	8.0±1.4
APCam11	Closed loop (n=46)	8.0±0.6	7.4±0.6
	Control (n=40)	7.8±0.6	7.7±0.5
FastKids	Closed loop with Fiasp (n=25)	7.2±0.8	NA
	Closed loop with Novolog (n=25)	7.2±0.8	NA
AP@home04 – Phase 3	Closed loop with Fiasp (n=25)	7.4±0.8	NA
	Closed loop with Novolog (n=25)	7.4±0.8	NA
AP@home04 – Phase 4	Closed loop with Lyumjev (n=26)	7.1±0.9	NA
	Closed loop with Humalog (n=27)	7.1±0.9	NA

* when using CamAPS FX

Real-World Evidence

The sponsor also conducted analyses of real-world data to support the overall safety of CamAPS FX as well as specific features, such as Boost Mode and Ease-Off Mode. Real-world evidence (RWE) analyses were conducted in 9,869 users with type 1 diabetes who used the CamAPS FX app for a median of 265 days. Data analysis was performed using sensor glucose data collected between December 1, 2022, and November 30, 2023. This information was used to help support the safety and effectiveness of this device and support the substantial equivalence of CamAPS FX to its predicate device.

Specifically, this data provided information on the extended use (i.e., between 9-13 hours) of Boost mode, which was not utilized in the clinical studies. With the longer duration of use, there was no increase in reported severe hypoglycemia. However, as expected there was some increase in CGM % time below 70 mg/dL from 0.0% to around 1%. Similarly, RWE provided information on the extended use (i.e., between 9-13 hours) of Ease-off mode, which was not utilized in the clinical studies. While there was no increase in incidence of reported DKA, there was a gradual increase in CGM % time above range (>180 mg/dL) with longer duration of Ease-off mode use.

Finally, RWE provided data on use of personal glucose targets <90 mg/dL or >160 mg/dL which were not utilized in the clinical studies. As expected, use of these low or high glucose targets resulted in increased time below range and time above range, respectively. There was no association of higher/lower targets with increased incidence of reported DKA/severe hypoglycemia.

Although use of Boost or Ease off mode for more than 9 hours, or personal glucose targets at the very high or low ends did appear to be associated with an increase in time below or above range, use of these settings may be appropriate for certain clinical circumstances. For example, use of a lower personal target may be appropriate in pregnancy to achieve tighter glycemic targets, and use of Boost mode may be appropriate for patients who need to take steroid medications for a short period of time. The use of these features is important to allow for custom use of the device to adapt to the clinical needs and characteristics of the intended user population. Appropriate warnings and information regarding use of Boost mode, Ease-off mode, and personalized glucose targets are included in the User Manual, including examples of when to use these modes appropriately. All users are cautioned to discuss use of these settings with guidance from their healthcare provider.

Human Factors

Human factors validation testing was conducted with CamAPS FX installed on an Android phone. A total of two formative studies were conducted and the results were used to inform the user interface design, use-related risk analysis, and summative testing protocol. The summative human factors validation study was performed on the final device design with 50 representative participants which included adult users (18 years and older), adolescent users (13-17 years) with their caregivers, and pediatric users (2-12 years) with their caregivers. All study participants received in-app training that was consistent with the training that patients would receive with the commercial product. Simulated use testing assessed the usability and risk mitigations of the device by providing sufficient clinical context to simulate actual use scenarios representing all critical device tasks. Results of the study supported the substantial equivalence of CamAPS FX to its predicate.

User and Provider Training

Physician and user training as per the sponsor-provided training materials is important to ensure safe use of the device. When a new user (including healthcare professionals and caregivers) downloads the app and signs into the CamAPS FX for the first time, they will be immediately offered in-App training. This mandatory in-app training is designed to orient the user to the functionality of the app, covering all critical tasks that the user will need to perform safely when

using the app. The training includes mock tasks to pair with the pump and CGM in order to practice tasks such as giving a meal bolus and using Boost and Ease-off etc. without impacting on the user's actual insulin delivery. Once the required in-app training is completed, the user can choose to remain in virtual mode to use the app as a training resource.

Users are able to revisit the in-App training at any time as well as review additional training information within the "Help" menu of the app. They are also able to download training factsheets as a resource should they wish to do so. Additional training resources (animations, factsheets and webinars) are available via the CamDiab website.

Hazard Analysis

A comprehensive hazard analysis was provided for this device, in which design inputs and outputs, risks, and risk mitigations for software and interoperable hardware components associated with the safe and effective functioning of the device were reviewed. The hazard analysis provided in this submission accounted for the unique design elements, intended use, and risks of the CamAPS FX design. In particular, this hazard analysis accounted for the risks associated with interoperability between the software device developed by the sponsor and commercial off-the-shelf (COTS) hardware device it was installed on, as well as with other third-party interoperable devices. This analysis identified hazards which could reasonably be anticipated to impact the proper use of the device, traced all identified risks to adequate design controls, and demonstrated that design features were appropriately implemented and validated.

Data Logging

The sponsor provided software and bench testing to demonstrate that the device is able to record critical events, including information related to its state (e.g., commanded delivery rates/volumes, all algorithm calculations, open loop/closed loop mode, power on/off events), user inputs, and device settings. In addition, the sponsor detailed the specific information that they would collect from all interoperable components connected to CamAPS FX including the iCGM and ACE pump components. All log entries are time stamped with the time of occurrence in originating device. These protocols were reviewed and found to be adequate.

Predetermined Change Control Plan (PCCP)

A predetermined change control plan (PCCP) for integrating with potential interoperable devices in the future 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-RevA-US Predetermined Change Control Plan" and "P-606-Regulatory Filing Determination for FDA") 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-RevA-US Predetermined Change Control Plan" and "P-606-Regulatory Filing Determination for FDA" 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-RevA-US Predetermined Change Control Plan" and "P-606-Regulatory Filing Determination for FDA" 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)).

Cybersecurity

Detailed information on cybersecurity of the device was reviewed and found to be acceptable. The sponsor provided detailed information relating to the penetration testing conducted as part of their cybersecurity evaluation. The sponsor provided a software bill of materials, which provided details on all software used in the device and the COTS hardware platform that the Software-as-a-Medical-device (SAMD) was installed on. This included all manufacturer-developed, commercially licensed, open source, partner and off-the-shelf software components (including firmware, as relevant), along with an identification of the hardware runtime environment in which each resides, with relevant version and/or model information, as well as details on whether each component was actively supported by its manufacturer or legacy licensed.

Postmarket Surveillance Study

There is uncertainty remaining regarding the risk/benefit profile of the device when used in the broader intended use population. While the premarket clinical studies provided to support the 510(k) showed some benefits, the study included mostly well-educated white users, and they were not adequately powered to assess differences in the rates of safety events (e.g., diabetic ketoacidosis and severe hypoglycemia). Further, pump-naïve users were underrepresented in the studies, and there is residual uncertainty surrounding the safety of certain personalized glucose targets as well as the use of "Boost" and "Ease-Off" mode. Finally, although multiple studies were leveraged to support the substantial equivalence of CamAPS FX, the studies consisted of

various designs, durations, and study populations (i.e., different age groups were targeted in different studies), which contributes to the uncertainty in the device risk/benefit profile across the entire intended use population. Accordingly, a postmarket surveillance study will be ordered by FDA to confirm understanding of safety.

VIII Proposed Labeling:

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

IX Conclusion:

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