

**K232603 CamAPS FX**May 23, 2024  
269 days to decisionK232603 · Product code: **QJI** · Chemistry  
Source: <https://www.510kdatabase.net/k232603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Aug 28, 2023
Decision date	May 23, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

Company	<b>Camdiab , Ltd.</b>
Location	London, GB
Contact	Roman Hovorka
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

Consulting firm	<b>Mcra, LLC</b>
Contact	Nima Akhlaghi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**CLINICAL EVIDENCE - NCT00910767****Closing the Loop in Adults With Type 1 Diabetes**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	12 patients (actual)
Study sites	1 site
Condition studied	Type 1 Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Open label
Completion date	Jul 1, 2009
Sponsor	University of Cambridge (Other)

**Primary outcome**

Percentage of plasma glucose values in target (3.9 - 8.0 mmol/L)

**Secondary outcome**

Percentage of CGM (continuous glucose monitoring) values in target (3.9-8.0 mmol/L)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT00910767](https://clinicaltrials.gov/study/NCT00910767)