FDA 510(k) Premarket Notification

K252770 iLet ACE Pump

CLEARED

Sep 29, 2025
27 days to decision

K252770 · Product code: **QFG** · Chemistry
Source: https://www.510kdatabase.net/k252770/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Sep 2, 2025
Decision date	Sep 29, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beta Bionics, Inc.**
Location	Concord, MA, US
Contact	Liz Cooper
Website	https://www.betabionics.com
510(k) history	6 submissions · 6 cleared · 2023-2026

Beta Bionics, Inc. develops automated insulin delivery systems for type 1 diabetes management. The company is dedicated to simplifying diabetes care through innovative technology. Beta Bionics operates with a manufacturing facility in Concord, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2023. All submissions focus on Chemistry devices. The latest clearance occurred in 2026, confirming the company remains actively engaged in regulatory submissions. Beta Bionics specializes in Chemistry devices, including the iLet B...

CLINICAL EVIDENCE - NCT04200313

The Insulin-Only Bionic Pancreas Pivotal Trial

Status	Completed
Enrollment	440 patients (actual)
Study sites	16 sites
Condition studied	Diabetes Mellitus; Type 1 Diabetes; Diabetes Mellitus, Type 1
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jan 14, 2022
Sponsor	Jaeb Center for Health Research (Other)

Primary outcome

HbA1c

Secondary outcome

Non-inferiority for CGM-measured Time <54 mg/dL (Key Secondary Endpoint)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04200313