FDA 510(k) Premarket Notification

K253976 iLet ACE Pump

CLEARED

Apr 30, 2026
139 days to decision

K253976 · Product code: **QFG** · Chemistry
Source: https://www.510kdatabase.net/k253976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Dec 12, 2025
Decision date	Apr 30, 2026
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Beta Bionics, Inc.**
Location	Concord, MA, US
Contact	Douglas Ferguson
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...