

K231485 iLet® ACE PumpJun 21, 2023
29 days to decisionK231485 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k231485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	May 23, 2023
Decision date	Jun 21, 2023
Days to decision	29 days
Third-party review	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...
