

K231824 SmartBolus CalculatorOct 18, 2023
119 days to decisionK231824 · Product code: **QRX** · Chemistry
Source: <https://www.510kdatabase.net/k231824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Glucose Monitor Informed Insulin Dose Calculator (QRX)
Date received	Jun 21, 2023
Decision date	Oct 18, 2023
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Insulet Corporation
Location	Bedford, MA, US
Contact	Maria Brower
510(k) history	23 submissions · 23 cleared · 2005-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231824/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026