

K203772 Omnipod 5 SmartBolus CalculatorJan 27, 2022
400 days to decisionK203772 · Product code: **QRX** · Chemistry
Source: <https://www.510kdatabase.net/k203772/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Glucose Monitor Informed Insulin Dose Calculator (QRX)
Date received	Dec 23, 2020
Decision date	Jan 27, 2022
Days to decision	400 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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