

K220394 SmartAdjust(TM) technologyAug 19, 2022
189 days to decisionK220394 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k220394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interoperable Automated Glycemic Controller (QJI)
Date received	Feb 11, 2022
Decision date	Aug 19, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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