

K191679 Omnipod DASH Insulin Management System with interoperable technologySep 20, 2019
88 days to decisionK191679 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k191679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Jun 24, 2019
Decision date	Sep 20, 2019
Days to decision	88 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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