

K192659 Omnipod Insulin Management System, Omnipod DASH Insulin Management SystemOct 21, 2019
26 days to decisionK192659 · Product code: **LZG** · General Hospital
Source: <https://www.510kdatabase.net/k192659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Sep 25, 2019
Decision date	Oct 21, 2019
Days to decision	26 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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