

K182630 Omnipod Insulin Management System, Omnipod DASH Insulin Management System

Jan 8, 2019
106 days to decision

K182630 · Product code: **LZG** · General Hospital
Source: <https://www.510kdatabase.net/k182630/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Sep 24, 2018
Decision date	Jan 8, 2019
Days to decision	106 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182630/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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