

K211575 Omnipod® Insulin Management System, Omnipod DASH® Insulin Management SystemAug 13, 2021
84 days to decisionK211575 · Product code: **LZG** · Chemistry
Source: <https://www.510kdatabase.net/k211575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	May 21, 2021
Decision date	Aug 13, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211575/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026