

**K203768 Omnipod 5 ACE Pump (Pod)**Jan 27, 2022  
400 days to decisionK203768 · Product code: **QFG** · Chemistry  
Source: <https://www.510kdatabase.net/k203768/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Dec 23, 2020
Decision date	Jan 27, 2022
Days to decision	400 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203768/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026