

K213536 DEKA ACE Pump SystemJul 25, 2023
627 days to decisionK213536 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k213536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Nov 5, 2021
Decision date	Jul 25, 2023
Days to decision	627 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Deka Research and Development
Location	Manchester, NH, US
Contact	Paul Smolenski
510(k) history	11 submissions · 11 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213536/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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