

K252757 CeQur Simplicity™ On-Demand Insulin Delivery SystemApr 10, 2026
224 days to decisionK252757 · Product code: **OPP** · Chemistry
Source: <https://www.510kdatabase.net/k252757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Insulin Bolus (OPP)
Date received	Aug 29, 2025
Decision date	Apr 10, 2026
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CeQur SA
Location	Horw Luzern, CH
Contact	Michael Simpson
510(k) history	3 submissions · 3 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252757/> 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 13, 2026