

K243273 CeQur Simplicity™ On-Demand Insulin Delivery SystemNov 13, 2024
28 days to decisionK243273 · Product code: **OPP** · Chemistry
Source: <https://www.510kdatabase.net/k243273/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Pump, Infusion, Insulin Bolus (OPP) |
| Date received | Oct 16, 2024 |
| Decision date | Nov 13, 2024 |
| Days to decision | 28 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/k243273/> 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