

K163357 OneTouch Via On-Demand Insulin Delivery SystemJun 7, 2017
189 days to decisionK163357 · Product code: **OPP** · General Hospital
Source: <https://www.510kdatabase.net/k163357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin Bolus (OPP)
Date received	Nov 30, 2016
Decision date	Jun 7, 2017
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifescan Europe, A Division of Cilag GmbH
Location	Zug, CH
Contact	Kirsten Franco
510(k) history	1 submissions · 1 cleared · 2017-2017

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