

K122686 ACCU-CHEK ULTRAFLEX INFUSION SETNov 16, 2012
73 days to decisionK122686 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k122686/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 4, 2012
Decision date	Nov 16, 2012
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diabetes Care AG
Location	Burgdorf, CH
Contact	CATHERINE GREEN
510(k) history	1 submissions · 1 cleared · 2012-2012

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