

K143446 Accu-Chek FlexLink Plus infusion setAug 13, 2015
254 days to decisionK143446 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k143446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 2, 2014
Decision date	Aug 13, 2015
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics GmbH
Location	Mannheim, DE
Contact	Alexander Ruegner
510(k) history	5 submissions · 5 cleared · 1998-2026

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