

K101196 ACCU-CHEK ULTRFLEX INFUSION SETAug 27, 2010
120 days to decisionK101196 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k101196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 29, 2010
Decision date	Aug 27, 2010
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	Scott Thiel
510(k) history	264 submissions · 263 cleared · 1999-2013

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