FDA 510(k) Premarket Notification

K101196 ACCU-CHEK ULTRFLEX INFUSION SET

CLEARED

Aug 27, 2010
120 days to decision

K101196 · 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