

K070189 ACCU-CHEK ULTRAFLEX INFUSION SETFeb 21, 2007
30 days to decisionK070189 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k070189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jan 22, 2007
Decision date	Feb 21, 2007
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Disetronic Medical Systems AG
Location	Fort Myers, FL, US
Contact	MIKE FLIS
510(k) history	12 submissions · 12 cleared · 2000-2010

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