

**K003977 DISETRONIC RAPID SUBCUTANEOUS INFUSION SET  
AND DISTERONIC RAPID D SUBCUTANEOUS INFUSION SET**

Feb 15, 2001  
55 days to decision

K003977 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k003977/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 22, 2000
Decision date	Feb 15, 2001
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Disetronic Medical Systems AG</b>
Location	Fort Myers, FL, US
Contact	DAVID E CHADWICK
510(k) history	12 submissions · 12 cleared · 2000-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k003977/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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