

**K002138 PARADIGM SILHOUETTE, MODELS MMT-377, 378,  
379, 380**Aug 29, 2000  
43 days to decisionK002138 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k002138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 17, 2000
Decision date	Aug 29, 2000
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maersk Medical A/S</b>
Location	Sylmar, CA, US
Contact	JENNIFER LYONS
510(k) history	9 submissions · 9 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002138/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated July 1, 2026