

**K082818 SUBCUTANEOUS NEEDLE INFUSION SET**Dec 23, 2008  
89 days to decisionK082818 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k082818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 25, 2008
Decision date	Dec 23, 2008
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Marcal Medical, Inc.</b>
Location	Apollo Beach, FL, US
Contact	ARTHUR WARD
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082818/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 23, 2026