

**K080865 FAST1 INTRAOSSEOUS INFUSION SYSTEM**Apr 24, 2008  
27 days to decisionK080865 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k080865/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 28, 2008
Decision date	Apr 24, 2008
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pyng Medical Corp.</b>
Location	Richmond, B.C., CA
Contact	MAYA BUTTERFIELD
510(k) history	5 submissions · 5 cleared · 1997-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080865/> 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 8, 2026