

**K130487 FASTRESPONDER STERNAL INTRAOSSEOUS
DEVICE**Jun 25, 2013
120 days to decisionK130487 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k130487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 25, 2013
Decision date	Jun 25, 2013
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pyng Medical Corp.
Location	Richmond, B.C., CA
Contact	Michele Tyler
510(k) history	5 submissions · 5 cleared · 1997-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130487/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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