FDA 510(k) Premarket Notification

K130487 FASTRESPONDER STERNAL INTRAOSSEOUS DEVICE

CLEARED

Jun 25, 2013
120 days to decision

K130487 · 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