FDA 510(k) Premarket Notification

K100124 FASTX STERNAL INTRAOSSEOUS DEVICE

CLEARED

Aug 31, 2010
224 days to decision

K100124 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k100124/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 19, 2010
Decision date	Aug 31, 2010
Days to decision	224 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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