

**K111016 SAFEPORT MANIFOLD (TM) (OR STOPCOCK)**Jun 9, 2011  
58 days to decisionK111016 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k111016/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 12, 2011
Decision date	Jun 9, 2011
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Elcam Medical Acal</b>
Location	Phoenix, AZ, US
Contact	NATASHA EVRONYAN
510(k) history	16 submissions · 16 cleared · 2003-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111016/> 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 May 26, 2026