

**K060580 K-SHIELD PORT ACCESS INFUSION SET**Jun 6, 2006  
92 days to decisionK060580 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k060580/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 6, 2006
Decision date	Jun 6, 2006
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Kawasumi Laboratories, Inc.</b>
Location	Washington, DC, US
Contact	JACK PAVLO
510(k) history	11 submissions · 11 cleared · 2002-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060580/> 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 20, 2026