

**K000085 PORTSETT**Mar 17, 2000  
65 days to decisionK000085 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k000085/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 12, 2000
Decision date	Mar 17, 2000
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Portsett, Inc.</b>
Location	Rancho Santa Margarita, CA, US
Contact	SALVADORE F PALOMARES
510(k) history	1 submissions · 1 cleared · 2000-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000085/> 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 July 4, 2026