

**K972527 PHASEAL, SYSTEM FOR SEALED HANDLING OF CHEMOTHERAPEUTIC AGENTS**

Sep 18, 1997  
73 days to decision

K972527 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k972527/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 7, 1997
Decision date	Sep 18, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Quality System Consulting</b>
Location	Carlsbad, CA, US
Contact	FRED SCHLADOR
510(k) history	1 submissions · 1 cleared · 1997-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k972527/>. Data sourced from FDA 510(k) public records (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. - Generated July 5, 2026