

**K972100 VENTED EXTERNAL MALE URINARY  
CATHETER(VENTED CATH 5000)**Jul 31, 1997  
57 days to decisionK972100 · Product code: **EXJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k972100/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Jun 4, 1997
Decision date	Jul 31, 1997
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Advanced Care Medical Products</b>
Location	Novato, CA, US
Contact	STEVEN FAINSZTEIN
510(k) history	1 submissions · 1 cleared · 1997-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972100/> 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 1, 2026