

**K934266 COMFORT CATH SELF ADHERING MALE EXTERNAL  
CATHETER**Apr 19, 1994  
231 days to decisionK934266 · Product code: **EXJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k934266/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Aug 31, 1993
Decision date	Apr 19, 1994
Days to decision	231 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Sierra Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	ROBERT J KLUG, PHD
510(k) history	12 submissions · 12 cleared · 1979-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934266/> 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 May 27, 2026