

**K970966 COMFORT CATH CHOICE MALE EXTERNAL  
CATHETER**Apr 22, 1997  
36 days to decisionK970966 · Product code: **EXJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k970966/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Mar 17, 1997
Decision date	Apr 22, 1997
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970966/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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