

**K962384 COMFORT SHEATH REUSABLE MALE EXTERNAL
CATHETER**Jul 15, 1996
25 days to decisionK962384 · Product code: **EXJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k962384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Jun 20, 1996
Decision date	Jul 15, 1996
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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