

K964219 ZIP CONDOM CATHETERAug 11, 1997
293 days to decisionK964219 · Product code: **EYZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k964219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Urine Drainage, Closed, For Nonindwelling Catheter, Sterile (EYZ)
Date received	Oct 22, 1996
Decision date	Aug 11, 1997
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Goulter Medical, Inc.
Location	Concord, CA, US
Contact	DAVID W SCHLERF
510(k) history	1 submissions · 1 cleared · 1997-1997

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