

K964575 SYMPACATH HYDROGEL COATED FOLEYFeb 4, 1997
82 days to decisionK964575 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k964575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 14, 1996
Decision date	Feb 4, 1997
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rusch Intl.
Location	Jeffrey, NH, US
Contact	KARENANN J BROZOWSKI
510(k) history	43 submissions · 43 cleared · 1995-2003

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