

K935630 NORTAOct 7, 1994
318 days to decisionK935630 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k935630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 23, 1993
Decision date	Oct 7, 1994
Days to decision	318 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beiersdorf, Inc.
Location	Mchenry, IL, US
Contact	KENNETH M NICOLL
510(k) history	45 submissions · 39 cleared · 1977-2009

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