

K971643 RUSCH BRILLANT BALLOON CATHETEROct 7, 1997
155 days to decisionK971643 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k971643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	May 5, 1997
Decision date	Oct 7, 1997
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rusch Intl.
Location	Jeffrey, NH, US
Contact	JAMES R WHITNEY
510(k) history	43 submissions · 43 cleared · 1995-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026