

**K993063 RUSCH BRILLANT SILICONE FOLEY**Dec 9, 1999  
87 days to decisionK993063 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k993063/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 13, 1999
Decision date	Dec 9, 1999
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Rusch Intl.</b>
Location	Jeffrey, NH, US
Contact	JULIE A BEAUMONT
510(k) history	43 submissions · 43 cleared · 1995-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993063/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026