FDA 510(k) Premarket Notification

K993063 RUSCH BRILLANT SILICONE FOLEY

CLEARED

Dec 9, 1999
87 days to decision

K993063 · 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	**Rusch Intl.**
Location	Jeffrey, NH, US
Contact	JULIE A BEAUMONT
510(k) history	43 submissions · 43 cleared · 1995-2003