

**K980919 ALL SILICONE 2-WAY & 3-WAY FOLY BALLOON
CATHETER AND NELATON CATHETER**Mar 31, 1998
20 days to decisionK980919 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k980919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Mar 11, 1998
Decision date	Mar 31, 1998
Days to decision	20 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fortune Medical Instrument Corp.
Location	Taipei Hsien, TW
Contact	KAREN U SALINAS
510(k) history	6 submissions · 6 cleared · 1998-2003

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