

**K021142 ALL SILICONE HEMATURIA CATHETER, MODELS
4861, 4862, 4863, 4864, 4865**Oct 1, 2002
175 days to decisionK021142 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k021142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Apr 9, 2002
Decision date	Oct 1, 2002
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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