

K013276 ALL-SILICONE FOLEY BALLOON CATHETER (TWO WAYFeb 15, 2002
137 days to decisionK013276 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k013276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Oct 1, 2001
Decision date	Feb 15, 2002
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary
Other names	THREE WAY, RADIOPAQUE)

APPLICANT

Company	Sewoon Medical Co., Ltd.
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	1 submissions · 1 cleared · 2002-2002

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