

**K905042 COMFORT SLEEVED ALL SILICONE FOLEY
CATHETER**Jan 18, 1991
72 days to decisionK905042 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k905042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 7, 1990
Decision date	Jan 18, 1991
Days to decision	72 days
Third-party review	No

APPLICANT

Company	Rochester Medical Corp.
Location	Rochester, MN, US
Contact	RICHARD D FRYAR
510(k) history	13 submissions · 13 cleared · 1990-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905042/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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