

K944382 ORION ALL SILICONE FOLEY CATHETERDec 6, 1994
90 days to decisionK944382 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k944382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 7, 1994
Decision date	Dec 6, 1994
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Regulatory & Marketing Services, Inc.
Location	Palm Harbor, FL, US
Contact	PATRICK J LAMB
510(k) history	21 submissions · 17 cleared · 1993-1996

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