

**K944376 ORION ALL SILICONE ELASTOMER COATED  
CATHETER**Nov 30, 1994  
84 days to decisionK944376 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k944376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 7, 1994
Decision date	Nov 30, 1994
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944376/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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