

**K082815 WELL LEAD SILICONE AND LATEX FOLEY  
CATHETERS**Oct 8, 2008  
13 days to decisionK082815 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k082815/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 25, 2008
Decision date	Oct 8, 2008
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Well Lead Medical Instruments</b>
Location	Apollo Beach, FL, US
Contact	HAN GUANG YUAN
510(k) history	4 submissions · 4 cleared · 2005-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082815/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026