

**K130908 DISPOSABLE SILICONE FOLEY CATHETER**Oct 3, 2013  
185 days to decisionK130908 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k130908/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Apr 1, 2013
Decision date	Oct 3, 2013
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangdong Baihe Medical Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130908/> 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 June 8, 2026