

**K140667 WELL LEAD HYDROPHILIC SILICONE FOLEY
CATHETER**Dec 15, 2014
272 days to decisionK140667 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k140667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Mar 18, 2014
Decision date	Dec 15, 2014
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Well Lead Medical Co., Ltd.
Location	Apollo Beach, FL, US
Contact	HAN GUANG YUAN
510(k) history	17 submissions · 17 cleared · 2009-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140667/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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