

**K133615 WELL LEAD PVC HYDROPHILIC URETHRAL
CATHETER**Feb 24, 2014
91 days to decisionK133615 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k133615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Nov 25, 2013
Decision date	Feb 24, 2014
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133615/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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