

K091516 WELL LEAD SILICONE CATHETER WITH TEMPERATURE SENSOROct 16, 2009
147 days to decisionK091516 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k091516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	May 22, 2009
Decision date	Oct 16, 2009
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091516/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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