

K202134 Well Lead All Silicone Foley Catheter with Temperature SensorApr 8, 2021
251 days to decisionK202134 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k202134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 31, 2020
Decision date	Apr 8, 2021
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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