

K173533 Duette 100% Silicone Dual-Balloon, Temperature-Sensing CatheterMar 29, 2018
134 days to decisionK173533 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k173533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 15, 2017
Decision date	Mar 29, 2018
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Poiesis Medical, LLC
Location	Jupiter, FL, US
Contact	Greg Wiita
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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