

K103371 COUDE/ OR TIEMANNMar 11, 2011
114 days to decisionK103371 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k103371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 17, 2010
Decision date	Mar 11, 2011
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Degania Silicone , Ltd.
Location	Emek Hayarden, IL
Contact	ZOYA LEE
510(k) history	19 submissions · 17 cleared · 1988-2026

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