

**K063442 ALL SILICONE FOLEY CATHETER, 2-WAY, 3-WAY,
WITH TEMPERATURE SENSOR**Mar 26, 2007
132 days to decisionK063442 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k063442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 14, 2006
Decision date	Mar 26, 2007
Days to decision	132 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063442/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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