

K243011 Silicone Urethral Catheter (Silicone Urethral Catheter)Jun 16, 2025
263 days to decisionK243011 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 26, 2024
Decision date	Jun 16, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Ecan Medical Co., Ltd.
Location	Guangzhou, CN
Contact	Liuyuan Han
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243011/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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