

K182463 Silicone Foley CatheterNov 6, 2019
422 days to decisionK182463 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 10, 2018
Decision date	Nov 6, 2019
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biosensors International Pte, Ltd.
Location	Singapore, SG
Contact	Lor Yen Yin
510(k) history	1 submissions · 1 cleared · 2019-2019

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