

**K201776 Foley Balloon Catheter for Urology**Dec 30, 2020  
184 days to decisionK201776 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201776/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jun 29, 2020
Decision date	Dec 30, 2020
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Apollon Co., Ltd.</b>
Location	Incheon, KR
Contact	Donghyuk Shin
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Tsd Life Sciences Co., Ltd.</b>
Contact	Hyeyoung Moon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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