

K202698 Prefilled SyringeDec 15, 2020
90 days to decisionK202698 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 16, 2020
Decision date	Dec 15, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Primecare Medical Co., Ltd.
Location	Hang Zhou, CN
Contact	Xueqing Yan
510(k) history	2 submissions · 2 cleared · 2020-2024

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