

**K253132 Single use stone retrieval balloons**Mar 6, 2026  
162 days to decisionK253132 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k253132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 25, 2025
Decision date	Mar 6, 2026
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Chuangxiang Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Lucius Long
510(k) history	13 submissions · 13 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253132/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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