

**K253013 Disposable Stone Retrieval Balloon Catheter**May 8, 2026  
231 days to decisionK253013 · Product code: **GCA** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k253013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection (GCA)
Date received	Sep 19, 2025
Decision date	May 8, 2026
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Soudon Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Junshi Wang
510(k) history	5 submissions · 5 cleared · 2023-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Vanhe Consulting Co., Ltd.</b>
Contact	Nick Wang

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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