

**K200173 Stone Retrieval Balloon**May 1, 2020  
99 days to decisionK200173 · Product code: **GCA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k200173/>**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	Jan 23, 2020
Decision date	May 1, 2020
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou AGS MedTech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Chunqi Han
510(k) history	17 submissions · 17 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200173/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026