

**K210660 Stone Retrieval Balloon Catheter**Apr 27, 2021  
54 days to decisionK210660 · Product code: **GCA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210660/>**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	Mar 4, 2021
Decision date	Apr 27, 2021
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anrei Medical (Hangzhou) Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Huibing Yang
510(k) history	6 submissions · 6 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210660/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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