

**K200481 Andorate Biopsy Valve, Andorate Biopsy Irrigator**Jun 18, 2020  
112 days to decisionK200481 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k200481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Feb 27, 2020
Decision date	Jun 18, 2020
Days to decision	112 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ga Health Company Limited</b>
Location	Hong Kong, CN
Contact	Cindy Ye
510(k) history	12 submissions · 12 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200481/> 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 26, 2026