

**K213095 andorate Suction Valve, andorate Air/Water Valve**Jan 12, 2022  
110 days to decisionK213095 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Sep 24, 2021
Decision date	Jan 12, 2022
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
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/k213095/> 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