

**K230280 ANDORATE® Suction Valve and ANDORATE® Biopsy Valve**May 11, 2023  
99 days to decisionK230280 · Product code: **KTI** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k230280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Feb 1, 2023
Decision date	May 11, 2023
Days to decision	99 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/k230280/> 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 14, 2026