

K232118 ANDORATE® Valve KitOct 16, 2023
91 days to decisionK232118 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Jul 17, 2023
Decision date	Oct 16, 2023
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232118/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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