

K230932 ANDORATE® Valve KitJul 7, 2023
95 days to decisionK230932 · Product code: **OCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Apr 3, 2023
Decision date	Jul 7, 2023
Days to decision	95 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

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