

K202838 Andorate Universal Endoscope Tip GuardMar 5, 2021
161 days to decisionK202838 · Product code: **OCU** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k202838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Storage Cover (OCU)
Date received	Sep 25, 2020
Decision date	Mar 5, 2021
Days to decision	161 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/k202838/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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