

K230588 Aer-O-Scope Colonoscope SystemAug 17, 2023
168 days to decisionK230588 · Product code: **FDF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Mar 2, 2023
Decision date	Aug 17, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gi View , Ltd.
Location	Washington, DC, US
Contact	Sharon Goldfarb
510(k) history	3 submissions · 3 cleared · 2014-2023

REGULATORY CONSULTANT

Consulting firm	Covington & Burling, Llp
Contact	Kristin Davenport

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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