

K183171 ScopeSeal Duodenoscope Protective DeviceOct 8, 2019
326 days to decisionK183171 · Product code: **ODB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k183171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Contamination Prevention Sheath (ODB)
Date received	Nov 16, 2018
Decision date	Oct 8, 2019
Days to decision	326 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gi Scientific, LLC
Location	Newbury, NH, US
Contact	Scott Miller
510(k) history	2 submissions · 2 cleared · 2014-2019

REGULATORY CONSULTANT

Consulting firm	Lakeshore Medical Device Consulting, LLC
Contact	Michele Lucey

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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