FDA 510(k) Premarket Notification

K183171 ScopeSeal Duodenoscope Protective Device

CLEARED

Oct 8, 2019
326 days to decision

K183171 · Product code: **ODB** · Gastroenterology & Urology
Source: 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