FDA 510(k) Premarket Notification

K213773 Insufflation Retention Device

CLEARED

Jul 21, 2022
231 days to decision

K213773 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213773/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Dec 2, 2021
Decision date	Jul 21, 2022
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bpendo, LLC**
Location	Norman, OK, US
Contact	Robert Holbrook
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Gilero, LLC**
Contact	James Fentress

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