FDA 510(k) Premarket Notification

K161791 Aer-O-Scope Colonoscope System

CLEARED

Aug 11, 2016
43 days to decision

K161791 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k161791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jun 29, 2016
Decision date	Aug 11, 2016
Days to decision	43 days
Third-party review	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