FDA 510(k) Premarket Notification

K220158 G-EYE System

CLEARED

Apr 11, 2022
82 days to decision

K220158 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k220158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jan 19, 2022
Decision date	Apr 11, 2022
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smart Medical Systems , Ltd.**
Location	Kfar Saba, IL
Contact	Adva Yoselzon
510(k) history	9 submissions · 9 cleared · 2006-2022

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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