FDA 510(k) Premarket Notification

CLEARED

K232997 EVIS Exera III Gastrointestinal Videoscope GIF-1TH190

Jun 19, 2024
271 days to decision

K232997 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232997/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Sep 22, 2023
Decision date	Jun 19, 2024
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Medical Systems Corporation**
Location	Melville, NY, US
Contact	Shinichiro Kawachi
510(k) history	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	**Olympus Corporation of the Americas**
Contact	Darlene R Hull

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