FDA 510(k) Premarket Notification

K213606 EvoEndo Single-Use Endoscopy System

CLEARED

Feb 14, 2022
91 days to decision

K213606 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213606/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Nov 15, 2021
Decision date	Feb 14, 2022
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**EvoEndo, Inc.**
Location	Centennial, CO, US
Contact	Heather Underwood
510(k) history	4 submissions · 4 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	**Proxima Clinical Research**
Contact	Isabella Schmitt

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