FDA 510(k) Premarket Notification

K244029 ROBOPERA (ER-R-002)

CLEARED

Sep 24, 2025
268 days to decision

K244029 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k244029/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Dec 30, 2024
Decision date	Sep 24, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ROBOPERA (ER-R-003)

APPLICANT

Company	**Endorobotics Co., Ltd.**
Location	Seoul, KR
Contact	Jihwan Kim
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Global Medical Standard Consulting Co., Ltd.**
Contact	JongHyun Kim

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