

K244029 ROBOPERA (ER-R-002)Sep 24, 2025
268 days to decisionK244029 · 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](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k244029/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026