FDA 510(k) Premarket Notification

K232327 Endorail

CLEARED

Mar 15, 2024
225 days to decision

K232327 · Product code: **ODC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Aug 3, 2023
Decision date	Mar 15, 2024
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Endostart S.R.L.**
Location	Certaldo, IT
Contact	Alessandro Tozzi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Qa & RA Medical Device Consulting , Ltd.**
Contact	Fabio De Pasquale

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

CLINICAL EVIDENCE - NCT05626738

Endorail in Long Lasting Colonoscopy

Status	Completed
Enrollment	38 patients (actual)
Study sites	3 sites
Condition studied	Colonoscopy; Incomplete Colonoscopy
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 24, 2023
Sponsor	Endostart srl (Industry)

Primary outcome

Percentage of Incomplete Long-lasting Colonscopies

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05626738