FDA 510(k) Premarket Notification

K242666 Fecobionics Anorectal System

CLEARED

Feb 12, 2025
160 days to decision

K242666 · Product code: **KLA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Esophageal Motility, Anorectal Motility, And Tube (KLA)
Date received	Sep 5, 2024
Decision date	Feb 12, 2025
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gi Bionics, LLC**
Location	San Diego, CA, US
Contact	Ricardo Villanueva
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Cygnus Regulatory**
Contact	Natalie Eagleburger

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

CLINICAL EVIDENCE - NCT03317938

Studies in Patients With Defecatory Disorders

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	236 patients (actual)
Study sites	2 sites
Condition studied	Fecal Incontinence; Constipation
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 31, 2024
Sponsor	Giome (Other)

Primary outcome

Decreased anorectal pressure assessed with the Fecobionics device

Secondary outcome

Decreased anorectal mechanical stress assessed with the Fecobionics device

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03317938