FDA 510(k) Premarket Notification

CLEARED

K243367 Minnesota Medical Technologies Fecal Incontinence Insert (My Miracle)

Jul 22, 2025
265 days to decision

K243367 · Product code: **PBP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rectal Insert (PBP)
Date received	Oct 30, 2024
Decision date	Jul 22, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Minnesota Medical Technologies**
Location	Stewartville, MN, US
Contact	Robert Anglin
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Sachs & Associates, Inc.**
Contact	Gregory Sachs

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

CLINICAL EVIDENCE - NCT03934463

Effects of an Anal Insert Device in Fecal Incontinence

Status	Completed
Enrollment	124 patients (actual)
Study sites	1 site
Condition studied	Fecal Incontinence
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 20, 2024
Sponsor	Minnesota Medical Technologies (Industry)

Primary outcome

Primary Effectiveness Endpoint

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03934463