

K251026 Regenesis EMS ChairAug 29, 2025
149 days to decisionK251026 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Apr 2, 2025
Decision date	Aug 29, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Medical Solutions
Location	Birmingham, AL, US
Contact	Mark Rohrer
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Hoy and Associates Regulatory Consulting
Contact	Jamie Owsiany

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/k251026/> 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 13, 2026