FDA 510(k) Premarket Notification

CLEARED

K251026 Regenesis EMS Chair

Aug 29, 2025
149 days to decision

K251026 · Product code: **KPI** · Gastroenterology & Urology
Source: 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