FDA 510(k) Premarket Notification

K250522 Multi4 System

CLEARED

Jun 27, 2025
126 days to decision

K250522 · Product code: **FAS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Feb 21, 2025
Decision date	Jun 27, 2025
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Multi4 Medical AB**
Location	J?nk?ping, SE
Contact	Miden Melle-Hannah
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Erin Gontang

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