FDA 510(k) Premarket Notification

K252024 NeurAxis IB-Stim (01-1020)

CLEARED

Oct 16, 2025
108 days to decision

K252024 · Product code: **QHH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252024/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-implanted Nerve Stimulator For Pain Associated With Irritable Bowel Syndrome (ibs) (QHH)
Date received	Jun 30, 2025
Decision date	Oct 16, 2025
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuraxis**
Location	Carmel, IN, US
Contact	Thomas Carrico
510(k) history	3 submissions · 3 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Dawn Norman

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