

K250451 NeurAxis IB-Stim (01-1020)May 15, 2025
86 days to decisionK250451 · Product code: **QHH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250451/>**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	Feb 18, 2025
Decision date	May 15, 2025
Days to decision	86 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250451/> 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 14, 2026