

**K241533 NeurAxis IB-Stim (01-1020)**Oct 30, 2024  
153 days to decisionK241533 · Product code: **QHH** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k241533/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-implanted Nerve Stimulator For Pain Associated With Irritable Bowel Syndrome (ibs) (QHH)
Date received	May 30, 2024
Decision date	Oct 30, 2024
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global, LLC</b>
Contact	Dawn Norman

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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