

K192731 ZIDA Wearable Neuromodulation SystemMar 19, 2021
539 days to decisionK192731 · Product code: **NAM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192731/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Non-implanted, For Urinary Incontinence (NAM)
Date received	Sep 27, 2019
Decision date	Mar 19, 2021
Days to decision	539 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exodus Innovations
Location	Sufa, IL
Contact	Isaac Oppenheim
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Msquared Associates, Inc.
Contact	Cherita James

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192731/> 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 27, 2026