

K233801 Nalu Neurostimulation System for Spinal Cord Stimulation

Aug 23, 2024
268 days to decisionK233801 · Product code: **GZB** · Neurology
Source: <https://www.510kdatabase.net/k233801/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Nov 29, 2023
Decision date	Aug 23, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Nalu Neurostimulation System for Peripheral Nerve Stimulation

APPLICANT

Company	Boston Scientific Neuromodulation
Location	Valencia, CA, US
Contact	Kaoru Lee Adair
510(k) history	9 submissions · 9 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	Boston Scientific Neuromodulation Corp.
Contact	Kaoru Lee Adair

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

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