

K183579 Nalu Neurostimulation Kit (Integrated, 40 cm: Single 8/Dual 8), Nalu Neurostimulation Kit (Ported, 2 cm: Single 8/Dual 8), Dual 8 Ported Nalu Implantable Pulse Generator with 40 cm Kit, 40 cm/ 60 cm Trial/Extension Lead Kits, Patient Kits and miscellaneous replacement kits

Mar 29, 2019
98 days to decision

K183579 · Product code: **GZF** · Neurology
Source: <https://www.510kdatabase.net/k183579/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF)
Date received	Dec 21, 2018
Decision date	Mar 29, 2019
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183579/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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