

K193033 GSI Audera ProApr 24, 2020
176 days to decisionK193033 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k193033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Oct 31, 2019
Decision date	Apr 24, 2020
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Grason Stadler
Location	Eden Prairie, MN, US
Contact	Brent Nissly
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

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/k193033/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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