

K242954 Integrity V500 (Integrity, Integrity with VEMP)Dec 19, 2024
85 days to decisionK242954 · Product code: **GWJ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k242954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Sep 25, 2024
Decision date	Dec 19, 2024
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vivosonic, Inc.
Location	Stamford, CT, US
Contact	Trevor Rocheleau
510(k) history	5 submissions · 5 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242954/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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