

K241228 TENSWaveAug 27, 2024
117 days to decisionK241228 · Product code: **GZJ** · Physical Medicine
Source: <https://www.510kdatabase.net/k241228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	May 2, 2024
Decision date	Aug 27, 2024
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zynex Medical Officer
Location	Englewood, CO, US
Contact	Sandgaard Thomas
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Zynex
Contact	Harrison Tanksley

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

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