FDA 510(k) Premarket Notification

K241228 TENSWave

CLEARED

Aug 27, 2024
117 days to decision

K241228 · 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