FDA 510(k) Premarket Notification

K252767 actiTENS mini

CLEARED

Jan 16, 2026
140 days to decision

K252767 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k252767/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Aug 29, 2025
Decision date	Jan 16, 2026
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sublimed**
Location	Moirans, FR
Contact	Adrien Hallet
510(k) history	2 submissions · 2 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy**
Contact	Rob Packard

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