

K252951 Genesis Sleep

Dec 31, 2025
106 days to decision

K252951 · Product code: **QJQ** · Neurology
Source: <https://www.510kdatabase.net/k252951/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Electrotherapy Stimulator To Treat Insomnia And/or Anxiety (QJQ)
Date received	Sep 16, 2025
Decision date	Dec 31, 2025
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurofield, Inc.
Location	Bishop, CA, US
Contact	Nicholas Dogris
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Vision28
Contact	Tom Renner

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