

K230826 Modius SleepOct 27, 2023
217 days to decisionK230826 · Product code: **QJQ** · Neurology
Source: <https://www.510kdatabase.net/k230826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Electrotherapy Stimulator To Treat Insomnia And/or Anxiety (QJQ)
Date received	Mar 24, 2023
Decision date	Oct 27, 2023
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurovalens , Ltd.
Location	Portglenone, GB
Contact	Jason McKeown
510(k) history	1 submissions · 1 cleared · 2023-2023

CLINICAL EVIDENCE - NCT04595968**Electrical Vestibular Nerve Stimulation (VeNS) Compared to Sham Control As a Means of Improving Glycemic Control in Adults with Type 2 Diabetes Mellitus**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	267 patients (actual)
Study sites	16 sites
Condition studied	Type 2 Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Aug 6, 2024
Sponsor	Neurovalens Ltd. (Industry)

Primary outcome

Change in glycated hemoglobin (HbA1c)

Secondary outcome

Participants who achieve HbA1c targets

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04595968