

K243289 ADDNOX (BPSPM1)Jan 16, 2025
90 days to decisionK243289 · Product code: **QGL** · Neurology
Source: <https://www.510kdatabase.net/k243289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcutaneous Nerve Stimulator For Adhd (QGL)
Date received	Oct 18, 2024
Decision date	Jan 16, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nu Eyne Co., Ltd.
Location	Seoul, KR
Contact	Dahee Kim
510(k) history	5 submissions · 5 cleared · 2019-2025

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