

**K213629 SMILE**Feb 12, 2023  
452 days to decisionK213629 · Product code: **QGL** · Neurology  
Source: <https://www.510kdatabase.net/k213629/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcutaneous Nerve Stimulator For Adhd (QGL)
Date received	Nov 17, 2021
Decision date	Feb 12, 2023
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nu Eyne Co., Ltd.</b>
Location	Seoul, KR
Contact	Dong Seong Lee
510(k) history	5 submissions · 5 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213629/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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