FDA 510(k) Premarket Notification

K213629 SMILE

CLEARED

Feb 12, 2023
452 days to decision

K213629 · Product code: **QGL** · Neurology
Source: https://www.510kdatabase.net/k213629/

SUBMISSION DETAILS

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

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