

K211380 ElixirJul 30, 2021
87 days to decisionK211380 · Product code: **PCC** · Neurology
Source: <https://www.510kdatabase.net/k211380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	May 4, 2021
Decision date	Jul 30, 2021
Days to decision	87 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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