

K234029 CEFALY Connected - OTC, CEFALY Connected - RxJul 18, 2024
211 days to decisionK234029 · Product code: **PCC** · Neurology
Source: <https://www.510kdatabase.net/k234029/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Dec 20, 2023
Decision date	Jul 18, 2024
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cefaly Technology
Location	Herstal, BE
Contact	Jennifer Trainor
510(k) history	6 submissions · 6 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Elexes Medical Consulting
Contact	Parul Chansoria

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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