

K212071 Cefaly Dual Enhanced with RFID - OTC, Cefaly Dual Enhanced with RFID - Rx, Cefaly Dual Connected - OTC, Cefaly Dual Connected - RxDec 13, 2022
529 days to decisionK212071 · Product code: **PCC** · Neurology
Source: <https://www.510kdatabase.net/k212071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Jul 2, 2021
Decision date	Dec 13, 2022
Days to decision	529 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Elexes Medical Consulting, LLC
Contact	Parul Chansoria

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

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