

K160237 CefalyMar 4, 2016
32 days to decisionK160237 · Product code: **PCC** · Neurology
Source: <https://www.510kdatabase.net/k160237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Feb 1, 2016
Decision date	Mar 4, 2016
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160237/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026