

**K171446 Cefaly Acute**Sep 15, 2017  
122 days to decisionK171446 · Product code: **PCC** · Neurology  
Source: <https://www.510kdatabase.net/k171446/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	May 16, 2017
Decision date	Sep 15, 2017
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cefaly Technology</b>
Location	Herstal, BE
Contact	Jean-Yves Mignolet
510(k) history	6 submissions · 6 cleared · 2016-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171446/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026