

K113037 PAIN-AIDMar 1, 2012
141 days to decisionK113037 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k113037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Oct 12, 2011
Decision date	Mar 1, 2012
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pdi Works, LLC
Location	Cleveland, TN, US
Contact	THU-HA DUNCAN
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113037/> 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 June 15, 2026