

K160115 Heat Pain ProJun 3, 2016
136 days to decisionK160115 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k160115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 19, 2016
Decision date	Jun 3, 2016
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Omron Healthcare, Inc.
Location	Vernon Hills, IL, US
Contact	RENEE Thornborough
510(k) history	68 submissions · 67 cleared · 1991-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160115/> 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 2, 2026