FDA 510(k) Premarket Notification

K172079 Avail

CLEARED

Oct 19, 2017
101 days to decision

K172079 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k172079/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jul 10, 2017
Decision date	Oct 19, 2017
Days to decision	101 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