

K171802 ALEVE Direct Therapy (ALEVE Direct Therapy TENS Device)Mar 7, 2018
261 days to decisionK171802 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k171802/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jun 19, 2017
Decision date	Mar 7, 2018
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	Cindy R. Abraham
510(k) history	46 submissions · 46 cleared · 2003-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171802/> 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 31, 2026