

**K152852 ALEVE Direct Therapy (ALEVE Direct Therapy TENS device)**Dec 22, 2015  
84 days to decisionK152852 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k152852/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 29, 2015
Decision date	Dec 22, 2015
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bayer Healthcare, LLC</b>
Location	New York, NY, US
Contact	William R Walsh
510(k) history	46 submissions · 46 cleared · 2003-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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