FDA 510(k) Premarket Notification

CLEARED

K152852 ALEVE Direct Therapy (ALEVE Direct Therapy TENS device)

Dec 22, 2015
84 days to decision

K152852 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k152852/

SUBMISSION DETAILS

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

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