FDA 510(k) Premarket Notification

CLEARED

K171802 ALEVE Direct Therapy (ALEVE Direct Therapy TENS Device)

Mar 7, 2018
261 days to decision

K171802 · 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