FDA 510(k) Premarket Notification

K163611 Pain Therapy Device

CLEARED

Sep 19, 2017
271 days to decision

K163611 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k163611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Dec 22, 2016
Decision date	Sep 19, 2017
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guangzhou Xinbo Electronic Co., Ltd.**
Location	Guangzhou, CN
Contact	Sammy Li
510(k) history	12 submissions · 12 cleared · 2017-2024