FDA 510(k) Premarket Notification

K160508 Electronic Pulse Stimulator

CLEARED

Nov 21, 2016
271 days to decision

K160508 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k160508/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Feb 24, 2016
Decision date	Nov 21, 2016
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Choice Electronic Technololgy Co., Ltd.**
Location	Shanghai, CN
Contact	Lei Chen
510(k) history	29 submissions · 29 cleared · 2007-2016