

K182671 Medi-Direct TENS PenSep 21, 2019
360 days to decisionK182671 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k182671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 26, 2018
Decision date	Sep 21, 2019
Days to decision	360 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jkh USA, LLC
Location	Diamond Bar, CA, US
Contact	Bill Quanqin Dai
510(k) history	9 submissions · 9 cleared · 2019-2021

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