

K161537 OTC TENS Device, Model PTS-IVOct 13, 2016
132 days to decisionK161537 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k161537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jun 3, 2016
Decision date	Oct 13, 2016
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Counter Scientific Development (Gz), Ltd.
Location	Bonita Springs, FL, US
Contact	WENDY POON
510(k) history	4 submissions · 4 cleared · 2014-2016

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