

K183674 Electronic Pulse StimulatorOct 11, 2019
288 days to decisionK183674 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k183674/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Dec 27, 2018
Decision date	Oct 11, 2019
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Leading Perfection Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Simon Hou
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Feiyang Drug & Medical Consulting Technical Service Group
Contact	Rain Yip

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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