

K190115 MHD TENSJun 19, 2019
146 days to decisionK190115 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k190115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 24, 2019
Decision date	Jun 19, 2019
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Minghuangda Electronic Co., Ltd.
Location	Baoan District, Shenzhen, CN
Contact	Zhang Guixiang
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

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

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