

K190009 Sunmas TENS & PMS (Model SM9187, SM9180L, SM9180S)

Dec 2, 2019
333 days to decision

K190009 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k190009/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 3, 2019
Decision date	Dec 2, 2019
Days to decision	333 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hong Qiangxing (Shenzhen) Electronics Limited
Location	Shanghai, CN
Contact	Xu Jianhua
510(k) history	9 submissions · 9 cleared · 2013-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190009/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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