

K192087 Combo Electrotherapy DeviceNov 1, 2019
88 days to decisionK192087 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k192087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 5, 2019
Decision date	Nov 1, 2019
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Roundwhale Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Kevin Zhang
510(k) history	7 submissions · 7 cleared · 2018-2024

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