

K210223 Transcutaneous Electrical Nerve StimulatorDec 15, 2021
321 days to decisionK210223 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k210223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 28, 2021
Decision date	Dec 15, 2021
Days to decision	321 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Top-Rank Health Care Co., Ltd.
Location	Shaoxing, CN
Contact	James Zhou
510(k) history	4 submissions · 4 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	Microkn Business Consulting (Shanghai) Co., Ltd.
Contact	Yuling Chen

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

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