

K243856 TENS AND EMS (TENS and Muscle Stimulator) (Model AS8012C,AS8016,AS8019,AS9020E,AS9026)

May 29, 2025
164 days to decision

K243856 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k243856/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Dec 16, 2024
Decision date	May 29, 2025
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Astec Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Connie Li
510(k) history	2 submissions · 2 cleared · 2020-2025

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Device record: <https://www.510kdatabase.net/k243856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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