

**K212377 Transcutaneous Electrical Applicator (TEA), Model  
SNM-FDC01**Apr 15, 2022  
256 days to decisionK212377 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k212377/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 2, 2021
Decision date	Apr 15, 2022
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ningbo Medkinetic Medical Device Co., Ltd.</b>
Location	Ningbo, CN
Contact	Zhang Wei
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.</b>
Contact	Zhang Wei

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212377/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026