

K230829 TENS7000 Rechargeable (Model:TENS7000 Rechargeable)Apr 26, 2023
30 days to decisionK230829 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k230829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Mar 27, 2023
Decision date	Apr 26, 2023
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Chongqing Rob Linka Science and Technology Co., Ltd.
Location	Chongqing, CN
Contact	Yixuan Li
510(k) history	4 submissions · 4 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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.netDevice record: <https://www.510kdatabase.net/k230829/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026