

K223428 Electronic Stimulator (Models: uLumb-9530A, uLumb-9531A, uLumb-9532A, uLumb-9533A, LQ-9525B, uNeck-9512A, uNeck-9515A, uNeck-9517B, uNeck-9518A, uNeck-9519A, uNeck-9521A, uNeck-9529A, LQ-9535A)May 8, 2023
175 days to decisionK223428 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k223428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Nov 14, 2022
Decision date	May 8, 2023
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Leqing Medical Instrument Co., Ltd.
Location	Shenzhen, CN
Contact	Shaodong Wang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Feiyong Drug & Medical Consulting Technical Service Group
Contact	Rain Yip

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

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