

**K221092 Transcutaneous Electrical Nerve Stimulator Model:
ST-304**Sep 13, 2022
153 days to decisionK221092 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k221092/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Apr 13, 2022 |
| Decision date | Sep 13, 2022 |
| Days to decision | 153 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Future Electronic Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Zhao Qihong |
| 510(k) history | 3 submissions · 3 cleared · 2022-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Qimmiq Medical Consulting Service Co., Ltd. |
| Contact | You Yijie |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221092/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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