

**K233492 EMS Neck Massager**Dec 20, 2023  
51 days to decisionK233492 · Product code: **NGX** · Neurology  
Source: <https://www.510kdatabase.net/k233492/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Stimulator, Muscle, Powered, For Muscle Conditioning (NGX) |
| Date received         | Oct 30, 2023   |
| Decision date         | Dec 20, 2023   |
| Days to decision      | 51 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Xiamen Comfier Technology Co., Ltd.</b> |
| Location       | Xiamen, CN                                 |
| Contact        | Petoula N/A                                |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023      |

**REGULATORY CONSULTANT**

---

|                 |  |
|-----------------|--|
| Consulting firm | <b>Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.</b> |
| Contact         | Reanny Wang  |

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233492/> 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 25, 2026