

**K183074 TENS and EMS Stimulator, TENS Stimulator**Jan 11, 2020  
432 days to decisionK183074 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k183074/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Stimulator, Muscle, Powered (IPF)  |
| Date received         | Nov 5, 2018                        |
| Decision date         | Jan 11, 2020                       |
| Days to decision      | 432 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Astek Technology , Ltd.</b>        |
| Location       | Tainan City, TW                       |
| Contact        | You-Jhe Lin                           |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183074/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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