

**K191938 FitRelief TENS&EMS Wireless Device**Aug 28, 2020  
406 days to decisionK191938 · Product code: **NGX** · Neurology  
Source: <https://www.510kdatabase.net/k191938/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Stimulator, Muscle, Powered, For Muscle Conditioning (NGX) |
| Date received         | Jul 19, 2019   |
| Decision date         | Aug 28, 2020   |
| Days to decision      | 406 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Heat IN A Click, LLC</b>           |
| Location       | Dania, FL, US                         |
| Contact        | Guy Levi                              |
| 510(k) history | 6 submissions · 6 cleared · 2015-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191938/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026