

K213197 MyOnyx SystemJun 17, 2022
261 days to decisionK213197 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k213197/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Muscle, Powered (IPF) |
| Date received | Sep 29, 2021 |
| Decision date | Jun 17, 2022 |
| Days to decision | 261 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Thought Technology , Ltd. |
| Location | Mchenry, IL, US |
| Contact | Suresh Sugirtharaja |
| 510(k) history | 22 submissions · 22 cleared · 1981-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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