

K180880 DARI HealthMar 7, 2019
338 days to decisionK180880 · Product code: **LXJ** · Physical Medicine
Source: <https://www.510kdatabase.net/k180880/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Interactive Rehabilitation Exercise Devices (LXJ) |
| Date received | Apr 3, 2018 |
| Decision date | Mar 7, 2019 |
| Days to decision | 338 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Scientific Analytics, Inc. |
| Location | Lincoln, NE, US |
| Contact | Joel Hungate |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------|
| Consulting firm | Ofw Law |
| Contact | Evan P. Phelps |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180880/> Data sourced from FDA 510(k) public records (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. - Generated June 22, 2026