

**K192474 VERA**Oct 10, 2019  
30 days to decisionK192474 · Product code: **LXJ** · Physical Medicine  
Source: <https://www.510kdatabase.net/k192474/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Special   |
| Device classification | Interactive Rehabilitation Exercise Devices (LXJ) |
| Date received         | Sep 10, 2019                                      |
| Decision date         | Oct 10, 2019                                      |
| Days to decision      | 30 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Reflexion Health, Inc.</b>         |
| Location       | San Diego, CA, US                     |
| Contact        | Walter Cordiglia                      |
| 510(k) history | 3 submissions · 3 cleared · 2015-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192474/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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