

**K240466 STARband 3D**Mar 15, 2024  
28 days to decisionK240466 · Product code: **OAN** · Neurology  
Source: <https://www.510kdatabase.net/k240466/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Special                             |
| Device classification | Orthosis, Cranial, Laser Scan (OAN) |
| Date received         | Feb 16, 2024                        |
| Decision date         | Mar 15, 2024                        |
| Days to decision      | 28 days                             |
| Third-party review    | No                                  |
| Combination product   | No                                  |
| PCCP authorized       | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---|
| Company        | <b>Orthomerica Products, Inc.</b>       |
| Location       | Washington, DC, US                      |
| Contact        | Najiba Katir                            |
| 510(k) history | 21 submissions · 21 cleared · 2000-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240466/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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