

**K180109 STARband, STARlight, St. Louis Band**Mar 1, 2018  
44 days to decisionK180109 · Product code: **OAN** · Neurology  
Source: <https://www.510kdatabase.net/k180109/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Jan 16, 2018
Decision date	Mar 1, 2018
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180109/> 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 26, 2026