

K081994 STARLIGHTSep 12, 2008
60 days to decisionK081994 · Product code: **OAN** · Neurology
Source: <https://www.510kdatabase.net/k081994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Jul 14, 2008
Decision date	Sep 12, 2008
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthomerica Products, Inc.
Location	Washington, DC, US
Contact	ALAN T SANDIFER
510(k) history	21 submissions · 21 cleared · 2000-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081994/> 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 May 26, 2026