

K161138 St. Louis BandJul 20, 2016
89 days to decisionK161138 · Product code: **OAN** · Neurology
Source: <https://www.510kdatabase.net/k161138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Apr 22, 2016
Decision date	Jul 20, 2016
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthomerica Products, Inc.
Location	Washington, DC, US
Contact	DAVID C. KERR
510(k) history	21 submissions · 21 cleared · 2000-2024

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