

K211376 STARbandAug 17, 2021
105 days to decisionK211376 · Product code: **OAN** · Neurology
Source: <https://www.510kdatabase.net/k211376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	May 4, 2021
Decision date	Aug 17, 2021
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211376/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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