FDA 510(k) Premarket Notification

K211376 STARband

CLEARED

Aug 17, 2021
105 days to decision

K211376 · 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