FDA 510(k) Premarket Notification

K133250 STARLIGHT

CLEARED

Jan 16, 2014
86 days to decision

K133250 · Product code: **OAN** · Neurology
Source: https://www.510kdatabase.net/k133250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Oct 22, 2013
Decision date	Jan 16, 2014
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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