FDA 510(k) Premarket Notification

K081994 STARLIGHT

CLEARED

Sep 12, 2008
60 days to decision

K081994 · 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