FDA 510(k) Premarket Notification

K021207 STARLIGHT

CLEARED

Jul 9, 2002
84 days to decision

K021207 · Product code: **OAN** · Neurology
Source: https://www.510kdatabase.net/k021207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Apr 16, 2002
Decision date	Jul 9, 2002
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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