FDA 510(k) Premarket Notification

K042039 FAMILY OF CRYSTAL 20 MONITORS MODEL #CS20-600,900,1300,1400,2400 & 120

CLEARED

Nov 17, 2004
111 days to decision

K042039 · Product code: **OLV** · Neurology
Source: https://www.510kdatabase.net/k042039/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Jul 29, 2004
Decision date	Nov 17, 2004
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cleveland Medical Devices, Inc.**
Location	Cleveland, OH, US
Contact	ROBERT N SCHMIDT
510(k) history	8 submissions · 8 cleared · 1995-2007