FDA 510(k) Premarket Notification

K010388 SONDREX P.A.L. SYSTEM

CLEARED

Dec 11, 2001
306 days to decision

K010388 · Product code: **HCC** · Neurology
Source: https://www.510kdatabase.net/k010388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Feb 8, 2001
Decision date	Dec 11, 2001
Days to decision	306 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ohmeda Medical**
Location	Madison, WI, US
Contact	ALBERTO F PROFUMO
510(k) history	120 submissions · 118 cleared · 1984-2013