FDA 510(k) Premarket Notification

CLEARED

K013389 DATEX-OHMEDA S/5 BIS MODULE, M-BIS AND ACCESSORIES

Jan 10, 2002
90 days to decision

K013389 · Product code: **OLW** · Neurology
Source: https://www.510kdatabase.net/k013389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Oct 12, 2001
Decision date	Jan 10, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Datex-Ohmeda**
Location	Tewksbury, MA, US
Contact	JOEL KENT
510(k) history	41 submissions · 41 cleared · 2000-2023