FDA 510(k) Premarket Notification

K052145 DATEX-OHMEDA S/5 BIS MODULE, E-BIS AND ACCESSORIES

CLEARED

Aug 23, 2005
15 days to decision

K052145 · Product code: **OLW** · Neurology
Source: https://www.510kdatabase.net/k052145/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Aug 8, 2005
Decision date	Aug 23, 2005
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare**
Location	Waukesha, WI, US
Contact	JOEL KENT
Website	http://www3.gehealthcare.com/en
510(k) history	168 submissions · 168 cleared · 2004-2026

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...