

K051883 DATEX-OHMEDA S/5 EEG MODULE, E-EEG AND DATEX-OHMEDA S/5 EEG HEADBOX, N-EEG AND ACCESSORIES.Aug 5, 2005
24 days to decisionK051883 · Product code: OLT · Neurology
Source: <https://www.510kdatabase.net/k051883/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Non-normalizing Quantitative Electroencephalograph Software (OLT) |
| Date received | Jul 12, 2005 |
| Decision date | Aug 5, 2005 |
| Days to decision | 24 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...