# K061907 MODIFICATION TO: DATEX-OHMEDA S/5 ENTROPY MODULE, E-ENTROPY AND ACCESSORIES

**CLEARED**

Mar 27, 2008
631 days to decision

K061907 · Product code: **OLW** · Neurology
Source: https://www.510kdatabase.net/k061907/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Index-generating Electroencephalograph Software (OLW) |
| Date received | Jul 5, 2006 |
| Decision date | Mar 27, 2008 |
| Days to decision | 631 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ge Healthcare** |
| Location | Waukesha, WI, US |
| Contact | JOEL C 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...