

**K013389 DATEX-OHMEDA S/5 BIS MODULE, M-BIS AND ACCESSORIES**Jan 10, 2002  
90 days to decisionK013389 · 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	<b>Datex-Ohmeda</b>
Location	Tewksbury, MA, US
Contact	JOEL KENT
510(k) history	41 submissions · 41 cleared · 2000-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013389/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 24, 2026