

**K090277 NATUS SLEEPWORKS, MODEL 104017**Apr 19, 2011  
804 days to decisionK090277 · Product code: **OLZ** · Neurology  
Source: <https://www.510kdatabase.net/k090277/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Feb 4, 2009
Decision date	Apr 19, 2011
Days to decision	804 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Excel-Tech Ltd. (Xltek)</b>
Location	Oakville, Ontario, CA
Contact	GOLDY SINGH
510(k) history	6 submissions · 6 cleared · 2008-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090277/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026