

K120260 ICTAJun 29, 2012
154 days to decisionK120260 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k120260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Jan 27, 2012
Decision date	Jun 29, 2012
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Excel-Tech Ltd. (Xltek)
Location	Oakville, Ontario, CA
Contact	DANIEL RAMIREZ
510(k) history	6 submissions · 6 cleared · 2008-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120260/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026