

**K010092 XLTEK EVOKED POTENTIAL HEADBOX, MODEL
REAL PATIENT EP-8-RP (PROPOSED)**Apr 2, 2001
81 days to decisionK010092 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k010092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Jan 11, 2001
Decision date	Apr 2, 2001
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Excel Tech. , Ltd.
Location	Oakville,Ontario, CA
Contact	SONJA MARKEZ
510(k) history	58 submissions · 53 cleared · 1985-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010092/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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