

K030489 BRM2 BRAIN MONITORMay 2, 2003
77 days to decisionK030489 · Product code: **OLT** · Neurology
Source: <https://www.510kdatabase.net/k030489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-normalizing Quantitative Electroencephalograph Software (OLT)
Date received	Feb 14, 2003
Decision date	May 2, 2003
Days to decision	77 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Brainz Instruments , Ltd.
Location	Auckland, NZ
Contact	CHRIS MANDER
510(k) history	3 submissions · 3 cleared · 2003-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030489/> 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 June 27, 2026