

K033010 BRM2 BRAIN MONITOROct 10, 2003
14 days to decisionK033010 · Product code: **OLT** · Neurology
Source: <https://www.510kdatabase.net/k033010/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Non-normalizing Quantitative Electroencephalograph Software (OLT) |
| Date received | Sep 26, 2003 |
| Decision date | Oct 10, 2003 |
| Days to decision | 14 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 |

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