

K071449 BRM3 BRAIN MONITORSep 14, 2007
113 days to decisionK071449 · Product code: **OMA** · Neurology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplitude-integrated Electroencephalograph (OMA)
Date received	May 24, 2007
Decision date	Sep 14, 2007
Days to decision	113 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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