

**K910771 DIGITRACE(TM) HOME MONIT COMP/ELB(TM) EEG
LUNCH BX**Dec 18, 1991
299 days to decisionK910771 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k910771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Feb 22, 1991
Decision date	Dec 18, 1991
Days to decision	299 days
Third-party review	No

APPLICANT

Company	New England Medical Instruments, Inc.
Location	Lexington, MA, US
Contact	JOHN R IVES
510(k) history	3 submissions · 3 cleared · 1991-1996

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