FDA 510(k) Premarket Notification

K060374 REFA, PHYSIOLOGICAL AMPLIFIER

CLEARED

May 30, 2006
106 days to decision

K060374 · Product code: **GWL** · Neurology
Source: https://www.510kdatabase.net/k060374/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Feb 13, 2006
Decision date	May 30, 2006
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Tms International BV**
Location	Evergreen, CO, US
Contact	DAVID W WAGNER
510(k) history	2 submissions · 2 cleared · 2006-2007

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k060374/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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