

K100683 NEUROLINK IP MODEL: PK1117Apr 9, 2010
30 days to decisionK100683 · Product code: **GWQ** · Neurology
Source: <https://www.510kdatabase.net/k100683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Mar 10, 2010
Decision date	Apr 9, 2010
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Natus Medical Incorporated
Location	Oakville, Ontario, CA
Contact	GOLDY SINGH
Website	http://www.natus.com/
510(k) history	10 submissions · 10 cleared · 2010-2018

Natus Medical Incorporated develops diagnostic and monitoring devices for neurological, sensory, and newborn care applications. The company operates with a manufacturing facility in Oakville, Ontario, Canada, and serves healthcare providers globally through neurodiagnostic and sensory screening solutions. Natus Medical received FDA 510(k) clearances from total submissions between 2010 and 2018. The company's cleared devices span General Hospital, Neurology, Ear/Nose/Throat, and Ophthalmic categories, including phototherapy systems, hearing screeners, neurophysiology monit...
