

K143440 Natus QuantumApr 20, 2015
139 days to decisionK143440 · Product code: **GWQ** · Neurology
Source: <https://www.510kdatabase.net/k143440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Dec 2, 2014
Decision date	Apr 20, 2015
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Natus Medical Incorporated
Location	Oakville, Ontario, CA
Contact	SANJAY MEHTA
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...
