

**K141446 ECHO-SCREEN III PRO HEARING SCREENER WITH
BARCODE SCANNER, ECHO-SCREEN III PRO HEARING
SCREENER WITHOUT BARCODE SCANNER,**Aug 22, 2014
81 days to decisionK141446 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k141446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jun 2, 2014
Decision date	Aug 22, 2014
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Natus Medical Incorporated
Location	Oakville, Ontario, CA
Contact	JUDY BUCKHAM
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...