

**K112881 NEXSTIM NAVIGATED BRAIN STIMULATION (NBS)
SYSTEM 4, NEXSTIM NBS SYSTEM 4 WITH NEXSPEECH(TM)**May 22, 2012
235 days to decisionK112881 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k112881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Sep 30, 2011
Decision date	May 22, 2012
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nexstim OY
Location	North Attleboro, MA, US
Contact	RAINER HARJUNPAA
510(k) history	2 submissions · 2 cleared · 2009-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112881/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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