

K143670 ICS CHARTR EP 200 WITH VEMPOct 23, 2015
303 days to decisionK143670 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k143670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Dec 24, 2014
Decision date	Oct 23, 2015
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gn Otometrics A/S
Location	Taastrup, DK
Contact	ANDERS RASMUSSEN
510(k) history	6 submissions · 6 cleared · 2004-2015

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