

K083399 ICS CHARTR EP 200Feb 20, 2009
95 days to decisionK083399 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k083399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Nov 17, 2008
Decision date	Feb 20, 2009
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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