

K071821 COILS, MODELS MCF-B65, MCF-75, MCF-125 AND COOL-B65Jul 27, 2007
24 days to decisionK071821 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k071821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Jul 3, 2007
Decision date	Jul 27, 2007
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tonica Elektronik A/S
Location	Farum, DK
Contact	LISE TERKELSEN
510(k) history	17 submissions · 17 cleared · 2006-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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