

K251125 MagVenture TMS Therapy SystemAug 11, 2025
122 days to decisionK251125 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k251125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Apr 11, 2025
Decision date	Aug 11, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	MagVenture A/S
Contact	Kirstine Klitgaard Schou

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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