

K252032 T65 (9016E061-)Jul 30, 2025
30 days to decisionK252032 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k252032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jun 30, 2025
Decision date	Jul 30, 2025
Days to decision	30 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	Freja Lüthje

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

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