

K260189 MagVenture Accelerated TMS (aTMS) Therapy SystemMay 22, 2026
120 days to decisionK260189 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k260189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jan 22, 2026
Decision date	May 22, 2026
Days to decision	120 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 Kjølner
510(k) history	18 submissions · 18 cleared · 2006-2026

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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