

K243869 Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire)Mar 17, 2025
90 days to decisionK243869 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k243869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Dec 17, 2024
Decision date	Mar 17, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Horizon® 3.0 TMS Therapy System (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0)

APPLICANT

Company	The Magstim Company Limited
Location	Carmarthenshire, GB
Contact	Alan Yik
Website	http://www.magstim.com/
510(k) history	3 submissions · 3 cleared · 2024-2025

The Magstim Company Limited is a neurotechnology company specializing in brain stimulation and neurophysiological monitoring solutions. Based in Carmarthenshire, GB, Magstim develops and manufactures transcranial magnetic stimulation (TMS), electroencephalography (EEG), and transcranial direct current stimulation (tDCS) systems for clinical and research applications. The company has received FDA 510(k) clearances from total submissions, with all submissions resulting in clearance. Magstim's cleared devices span neurology and physical medicine categories, with the most rec...