

K241518 Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire)

Aug 30, 2024
93 days to decisionK241518 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k241518/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	May 29, 2024
Decision date	Aug 30, 2024
Days to decision	93 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	Daniel Gregory
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...