

K220177 Magnus Neuromodulation System (MNS) with SAINT Technology, Model Number 1001KSep 1, 2022
223 days to decisionK220177 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k220177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Jan 21, 2022
Decision date	Sep 1, 2022
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Magnus Medical, Inc.
Location	Burlingame, CA, US
Contact	Brett Wingeier
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT03068715**Stanford Accelerated Intelligent Neuromodulation Therapy for Treatment-Resistant Depression (SAINT-TRD)**

Status	Completed
Enrollment	30 patients (actual)
Study sites	1 site
Condition studied	Treatment Resistant Depression
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Quadruple
Completion date	Jan 9, 2021
Sponsor	Stanford University (Other)

Primary outcome

Percentage Change in Montgomery-Åsberg Depression Rating Scale (MADRS) Score From Pre-treatment to 1-month Post-treatment.

Secondary outcome

Percentage Change in the Hamilton Rating Scale for Depression (HAM-D-17)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03068715