

K202537 ALTMS Magnetic Stimulation Therapy SystemNov 26, 2021
451 days to decisionK202537 · Product code: **OBP** · Neurology
Source: <https://www.510kdatabase.net/k202537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Sep 1, 2020
Decision date	Nov 26, 2021
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Remed Co., Ltd.
Location	Daejeon, KR
Contact	Yonsoo Nam
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	K-Biotech
Contact	Kyungyoon Kang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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