FDA 510(k) Premarket Notification

K202537 ALTMS Magnetic Stimulation Therapy System

CLEARED

Nov 26, 2021
451 days to decision

K202537 · 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