FDA 510(k) Premarket Notification

K202588 BNA Platform

CLEARED

Dec 7, 2020
90 days to decision

K202588 · Product code: **OLU** · Neurology
Source: https://www.510kdatabase.net/k202588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Normalizing Quantitative Electroencephalograph Software (OLU)
Date received	Sep 8, 2020
Decision date	Dec 7, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Elminda, Ltd.**
Location	Herzliya, IL
Contact	Keren Elghouzzi-Kazachinsky
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Biologics Consulting**
Contact	Donna-Bea Tillman

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

CLINICAL EVIDENCE - NCT01460394

Normative Data of Brain Network Activation in Adolescents and Young Adults

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	64 patients (actual)
Study sites	1 site
Condition studied	Healthy Controls
Study type	Observational
Completion date	Apr 1, 2012
Sponsor	ElMindA Ltd (Industry)

Primary outcome

Functional networks of brain activity in healthy individuals measured using analysis of EEG Event Related Potential (ERP) data

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01460394