FDA 510(k) Premarket Notification

K231337 EndeavorRx

CLEARED

Dec 13, 2023
219 days to decision

K231337 · Product code: **QFT** · Neurology
Source: https://www.510kdatabase.net/k231337/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapeutic Software For Attention Deficit Hyperactivity Disorder (QFT)
Date received	May 8, 2023
Decision date	Dec 13, 2023
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Akili Interactive Labs, Inc.**
Location	Boston, MA, US
Contact	Bhupinder Singh
510(k) history	3 submissions · 2 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Bhupinder Singh

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

CLINICAL EVIDENCE - NCT04897074

Software Treatment for Actively Reducing Severity of ADHD in Adolescents (STARS-ADHD-Adolescents)

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	165 patients (actual)
Study sites	14 sites
Condition studied	Attention Deficit Hyperactivity Disorder
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 1, 2022
Sponsor	Akili Interactive Labs, Inc. (Industry)

Primary outcome

Primary objective of this study is to evaluate the efficacy of AKL-T01 as determined by the change in a digitally assessed measure after 4 weeks of treatment

Secondary outcome

Secondary objective of this study is to evaluate the change in ADHD symptoms

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04897074