FDA 510(k) Premarket Notification

K233496 EndeavorOTC

CLEARED

Jun 14, 2024
228 days to decision

K233496 · Product code: **QFT** · Neurology
Source: https://www.510kdatabase.net/k233496/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapeutic Software For Attention Deficit Hyperactivity Disorder (QFT)
Date received	Oct 30, 2023
Decision date	Jun 14, 2024
Days to decision	228 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 - NCT05183919

Software Treatment for Actively Reducing Severity of ADHD in Adults (STARS ADHD Adult)

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	223 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	Jan 13, 2023
Sponsor	Akili Interactive Labs, Inc. (Industry)

Primary outcome

To evaluate the efficacy of AKL-T01 as determined by the change in a digitally assessed measure, Test of Variables of Attention (TOVA®) Attention Comparison Score (ACS), of sustained and selective attention, after 6 weeks of treatment with AKL-T01

Secondary outcome

To evaluate the change in ADHD symptoms, as determined by change in the ADHD Rating Scale-IV with adult prompts inattention sub-scale and total scale scores, after 6 weeks of treatment with AKL-T01

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05183919