

K233872 DaylightAug 30, 2024
267 days to decisionK233872 · Product code: **SCP** · Neurology
Source: <https://www.510kdatabase.net/k233872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Behavioral Therapy Device For Anxiety Disorders (SCP)
Date received	Dec 7, 2023
Decision date	Aug 30, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Big Health, Inc.
Location	San Francisco, CA, US
Contact	Reuben Lawson
510(k) history	2 submissions · 2 cleared · 2024-2024

CLINICAL EVIDENCE - NCT05748652**Generalized Anxiety Therapy Effectiveness**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	351 patients (actual)
Study sites	1 site
Condition studied	Generalized Anxiety Disorder
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Feb 28, 2024
Sponsor	Big Health Inc. (Industry)

Primary outcome

Generalized Anxiety Disorder Questionnaire (GAD-7)

Secondary outcome

Generalized Anxiety Disorder Questionnaire (GAD-7)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05748652