FDA 510(k) Premarket Notification

K223515 MamaLift Plus

CLEARED

Apr 22, 2024
517 days to decision

K223515 · Product code: **SAP** · Neurology
Source: https://www.510kdatabase.net/k223515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Behavioral Therapy Device For Depressive Disorders. (SAP)
Date received	Nov 22, 2022
Decision date	Apr 22, 2024
Days to decision	517 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curio Digital Therapeutics, Inc.**
Location	Princeton, NJ, US
Contact	Sidhartha Shankar
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT03024645

Be a Mom: Effectiveness of a Web-based Preventive Intervention for Postpartum Depression

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	1000 patients (estimated)
Study sites	1 site
Condition studied	PostPartum Depression
Primary purpose	Prevention
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Dec 31, 2021
Sponsor	University of Coimbra (Other)

Primary outcome

Number of women with clinically significant postpartum depressive symptoms (EPDS > 12) at 4 months postpartum

Secondary outcome

Changes from baseline in anxiety symptoms

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03024645