FDA 510(k) Premarket Notification

K213882 EarliPoint System

CLEARED

Jun 8, 2022
177 days to decision

K213882 · Product code: **QPF** · Neurology
Source: https://www.510kdatabase.net/k213882/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric Autism Spectrum Disorder Diagnosis Aid (QPF)
Date received	Dec 13, 2021
Decision date	Jun 8, 2022
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Earlitec Diagnostics, Inc.**
Location	Atlanta, GA, US
Contact	Thomas Ressemann
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Libramedical, Inc.**
Contact	Sew-Wah Tay

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

CLINICAL EVIDENCE - NCT03469986

A Multi-site Comparison of Social Visual Engagement to Clinical Diagnosis for Autism Spectrum Disorder

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	505 patients (actual)
Study sites	6 sites
Condition studied	Autism Spectrum Disorder
Study type	Observational
Completion date	May 31, 2019
Sponsor	EarliTec Diagnostics, Inc (Industry)

Primary outcome

Presence of Autism Spectrum Disorder

Secondary outcome

Social disability index

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03469986