

K230337 EarliPointJun 29, 2023
142 days to decisionK230337 · Product code: **QPF** · Neurology
Source: <https://www.510kdatabase.net/k230337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric Autism Spectrum Disorder Diagnosis Aid (QPF)
Date received	Feb 7, 2023
Decision date	Jun 29, 2023
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Earlitec Diagnostics, Inc.
Location	Atlanta, GA, US
Contact	Ryan Bormann
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](https://accessdata.fda.gov)

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