FDA 510(k) Premarket Notification

K253442 EarliPoint Assessment

CLEARED

Mar 5, 2026
155 days to decision

K253442 · Product code: **QPF** · Neurology
Source: https://www.510kdatabase.net/k253442/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric Autism Spectrum Disorder Diagnosis Aid (QPF)
Date received	Oct 1, 2025
Decision date	Mar 5, 2026
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Earlitec Diagnostics**
Location	Plymouth, MN, US
Contact	Ryan Bormann
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Amy Wolbeck

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

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Device record: https://www.510kdatabase.net/k253442/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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