

**K243891 EarliPoint System**Mar 26, 2025  
98 days to decisionK243891 · Product code: **QPF** · Neurology  
Source: <https://www.510kdatabase.net/k243891/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Special  |
| Device classification | Pediatric Autism Spectrum Disorder Diagnosis Aid (QPF) |
| Date received         | Dec 18, 2024   |
| Decision date         | Mar 26, 2025   |
| Days to decision      | 98 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Earlitec Diagnostics</b>           |
| Location       | Plymouth, MN, US                      |
| Contact        | Ryan Bormann                          |
| 510(k) history | 2 submissions · 2 cleared · 2025-2026 |

**REGULATORY CONSULTANT**

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|-----------------|-------------|
| Consulting firm | <b>RQM+</b> |
| Contact         | Amy Wolbeck |

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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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243891/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026