

K243558 Canvas DxApr 11, 2025
144 days to decisionK243558 · Product code: **QPF** · Neurology
Source: <https://www.510kdatabase.net/k243558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric Autism Spectrum Disorder Diagnosis Aid (QPF)
Date received	Nov 18, 2024
Decision date	Apr 11, 2025
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Cognoa, Inc.
Location	Palo Alto, CA, US
Contact	Sharief Taraman
510(k) history	2 submissions · 1 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Alexia Haralambous

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

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