

**K243294 Brainomix 360 e-ASPECTS**Feb 14, 2025  
119 days to decisionK243294 · Product code: **POK** · Radiology  
Source: <https://www.510kdatabase.net/k243294/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Oct 18, 2024
Decision date	Feb 14, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainomix Limited</b>
Location	Oxford, GB
Contact	Delanyo Mensah
510(k) history	12 submissions · 12 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243294/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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