

K221564 Brainomix 360 e-ASPECTSFeb 23, 2023
268 days to decisionK221564 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k221564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	May 31, 2022
Decision date	Feb 23, 2023
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brainomix Limited
Location	Oxford, GB
Contact	Gwilym Owen
510(k) history	12 submissions · 12 cleared · 2020-2025

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