

K242123 Brainomix 360 e-CTAJan 6, 2025
171 days to decisionK242123 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k242123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 19, 2024
Decision date	Jan 6, 2025
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242123/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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