

K251983 Brainomix 360 Triage StrokeAug 26, 2025
60 days to decisionK251983 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k251983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Jun 27, 2025
Decision date	Aug 26, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251983/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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