

K232496 Brainomix 360 Triage StrokeNov 21, 2023
96 days to decisionK232496 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k232496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Aug 17, 2023
Decision date	Nov 21, 2023
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232496/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026