

**K231195 Brainomix 360 Triage ICH**Jul 27, 2023  
91 days to decisionK231195 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k231195/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Apr 27, 2023
Decision date	Jul 27, 2023
Days to decision	91 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	Szrnka Zsolt
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/k231195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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