

**K231837 Brainomix 360 Triage LVO**Sep 28, 2023  
98 days to decisionK231837 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k231837/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Radiological Computer-assisted Triage And Notification Software (QAS) |
| Date received         | Jun 22, 2023  |
| Decision date         | Sep 28, 2023  |
| Days to decision      | 98 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231837/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026