

**K233875 Brainomix 360 e-Lung**May 13, 2024  
158 days to decisionK233875 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k233875/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 7, 2023
Decision date	May 13, 2024
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	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/k233875/> 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 13, 2026