

**K260406 Brainomix 360 Hyperdensity**Jun 12, 2026  
123 days to decisionK260406 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k260406/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 9, 2026
Decision date	Jun 12, 2026
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainomix Limited</b>
Location	Oxford, GB
Contact	Zsolt Sznka
510(k) history	13 submissions · 13 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260406/> 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 July 10, 2026