

**K231929 iQ-solutions**Dec 18, 2023  
171 days to decisionK231929 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k231929/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 30, 2023
Decision date	Dec 18, 2023
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sydney Neuroimaging Analysis Centre Pty, Ltd.</b>
Location	Camperdown, AU
Contact	Chenyu Wang
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pharmalex Pty, Ltd.</b>
Contact	Belinda Dowsett

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231929/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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