

**K250694 Scaida BrainCT-ICH (v1.0)**Nov 25, 2025  
263 days to decisionK250694 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k250694/>**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	Mar 7, 2025
Decision date	Nov 25, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MIhealth 360</b>
Location	Surrey, CA
Contact	Kumar Surender Sinwar
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Product Success, Inc.</b>
Contact	Sujata Ghatpande

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/k250694/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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