

**K252665 brAIIn™ Shoulder Positioning**Oct 20, 2025  
56 days to decisionK252665 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k252665/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 25, 2025
Decision date	Oct 20, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avatar Medical</b>
Location	Paris, FR
Contact	Adeline Francois
510(k) history	3 submissions · 3 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252665/> 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 13, 2026