

**K232231 QP-Brain®**Dec 13, 2023  
139 days to decisionK232231 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k232231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 27, 2023
Decision date	Dec 13, 2023
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quibim S.L.</b>
Location	Valencia, ES
Contact	Angel Alberich Bayarri
510(k) history	3 submissions · 3 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John J Smith

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

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