

**K230197 BoneMRI v1.6**Feb 22, 2023  
28 days to decisionK230197 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k230197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 25, 2023
Decision date	Feb 22, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mriguidance B.V.</b>
Location	Utrecht, NL
Contact	Marijn Van Stralen
510(k) history	3 submissions · 3 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Maxis Medical</b>
Contact	Sujith Shetty

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/k230197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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