

**K233030 BoneMRI**Mar 1, 2024  
158 days to decisionK233030 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k233030/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received         | Sep 25, 2023   |
| Decision date         | Mar 1, 2024  |
| Days to decision      | 158 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | Yes - Predetermined Change Control Plan (AI/SaMD)      |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mriguidance B.V.</b>               |
| Location       | Utrecht, NL                           |
| Contact        | David Sparks                          |
| 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](https://accessdata.fda.gov)

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