

**K221762 BoneMRI v1.4**Nov 16, 2022  
152 days to decisionK221762 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k221762/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received         | Jun 17, 2022   |
| Decision date         | Nov 16, 2022   |
| Days to decision      | 152 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mrlguidance B.V.</b>               |
| Location       | Utrecht, NL                           |
| Contact        | Marijn van Stralen                    |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

**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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