

**K203372 SyMRI**Nov 3, 2021  
352 days to decisionK203372 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k203372/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received         | Nov 16, 2020                                     |
| Decision date         | Nov 3, 2021                                      |
| Days to decision      | 352 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Syntheticmr AB</b>                 |
| Location       | Linkoping, SE                         |
| Contact        | Lisa Warnroth                         |
| 510(k) history | 6 submissions · 6 cleared · 2017-2021 |

**REGULATORY CONSULTANT**

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|-----------------|------------------------|
| Consulting firm | <b>Licensale, Inc.</b> |
| Contact         | Raymond Kelly          |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203372/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026