

**K222683 Fibroid Mapping Reviewer Application (FMRA)**Jul 17, 2023  
314 days to decisionK222683 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k222683/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Sep 6, 2022                                  |
| Decision date         | Jul 17, 2023                                 |
| Days to decision      | 314 days                                     |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Nesa Medtech Private Limited</b>   |
| Location       | Bengaluru, IN                         |
| Contact        | Sreekar Kothamachu                    |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------------|
| Consulting firm | <b>Medical Device Academy, Inc.</b> |
| Contact         | Rob Packard                         |

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/k222683/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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