FDA 510(k) Premarket Notification

**CLEARED**

# K222683 Fibroid Mapping Reviewer Application (FMRA)

Jul 17, 2023
314 days to decision

K222683 · 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

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

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Medical Device Academy, Inc.** |
| Contact | Rob Packard |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov