FDA 510(k) Premarket Notification

# K203182 SubtleMR

**CLEARED**

Feb 26, 2021
122 days to decision

K203182 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k203182/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Oct 27, 2020 |
| Decision date | Feb 26, 2021 |
| Days to decision | 122 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Subtle Medical, Inc.** |
| Location | Menlo Park, CA, US |
| Contact | Ajit Shankaranarayanan |
| 510(k) history | 9 submissions · 9 cleared · 2018-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Enzyme Corporation** |
| Contact | Jared Seehafer |

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