

**K203182 SubtleMR**Feb 26, 2021  
122 days to decisionK203182 · 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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Enzyme Corporation</b>
Contact	Jared Seehafer

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

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