

K241121 MICSI-RMTJul 17, 2024
85 days to decisionK241121 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k241121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 23, 2024
Decision date	Jul 17, 2024
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microstructure Imaging, Inc.
Location	Brooklyn, NY, US
Contact	Gregory Lemberskiy
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Enzyme Corporation
Contact	Michelle Rubin-Onur

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

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