

K211059 CereFlow™ V1.2Mar 31, 2023
721 days to decisionK211059 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k211059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 9, 2021
Decision date	Mar 31, 2023
Days to decision	721 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Translational Mri, LLC
Location	Los Angeles, CA, US
Contact	Zhihai Ricky Xiang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Rook Quality Systems Taiwan Branch
Contact	Andrew Wu

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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