FDA 510(k) Premarket Notification

K211059 CereFlow™ V1.2

CLEARED

Mar 31, 2023
721 days to decision

K211059 · 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