FDA 510(k) Premarket Notification

K232339 Augmented Reality Application

CLEARED

Feb 1, 2024
181 days to decision

K232339 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k232339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 4, 2023
Decision date	Feb 1, 2024
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sira Medical, Inc.**
Location	San Francisco, CA, US
Contact	Rick Beberman
510(k) history	1 submissions · 1 cleared · 2024-2024