FDA 510(k) Premarket Notification

K230252 OFIX MIS App

CLEARED

Sep 26, 2023
239 days to decision

K230252 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k230252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 30, 2023
Decision date	Sep 26, 2023
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthofix US, LLC**
Location	Lweisville, TX, US
Contact	Shant Aghyarian
510(k) history	4 submissions · 4 cleared · 2022-2025