

**K230252 OFIX MIS App**Sep 26, 2023  
239 days to decisionK230252 · 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	<b>Orthofix US, LLC</b>
Location	Lweisville, TX, US
Contact	Shant Aghyarian
510(k) history	4 submissions · 4 cleared · 2022-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230252/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026