

**K260321 HipGuide (V 1.0.0.0)**May 8, 2026  
98 days to decisionK260321 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k260321/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 30, 2026
Decision date	May 8, 2026
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthopedic Driven Imaging, LLC</b>
Location	Gainesville, FL, US
Contact	Michael McCaig
510(k) history	1 submissions · 1 cleared · 2026-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260321/> 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 June 8, 2026