

**K223318 Internal Joint Stabilizer - Elbow**May 10, 2023  
194 days to decisionK223318 · Product code: **OZI** · Orthopedic  
Source: <https://www.510kdatabase.net/k223318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Internal Hinged Elbow Fixator (OZI)
Date received	Oct 28, 2022
Decision date	May 10, 2023
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skeletal Dynamics, Inc.</b>
Location	Miami, FL, US
Contact	Alexandra Rodriguez Rojas
510(k) history	20 submissions · 20 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223318/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026