

K231447 Double Internal Joint Stabilizer- ElbowDec 15, 2023
211 days to decisionK231447 · Product code: **OZI** · Orthopedic
Source: <https://www.510kdatabase.net/k231447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Internal Hinged Elbow Fixator (OZI)
Date received	May 18, 2023
Decision date	Dec 15, 2023
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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