

K233574 Total Wrist Arthroplasty System (TWA)Jul 3, 2024
239 days to decisionK233574 · Product code: **JWJ** · Orthopedic
Source: <https://www.510kdatabase.net/k233574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, 3 Part Metal-plastic-metal Articulation, Semi-constrained (JWJ)
Date received	Nov 7, 2023
Decision date	Jul 3, 2024
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skeletal Dynamics
Location	Miami, FL, US
Contact	Alexandra Rodriguez
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233574/> 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 14, 2026