

K251395 The Rialto™ SI Fusion SystemJun 26, 2025
52 days to decisionK251395 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k251395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	May 5, 2025
Decision date	Jun 26, 2025
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Rong Guo
510(k) history	170 submissions · 159 cleared · 2000-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251395/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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