FDA 510(k) Premarket Notification

K251395 The Rialto™ SI Fusion System

CLEARED

Jun 26, 2025
52 days to decision

K251395 · 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