

K161210 RIALTO(TM) SI Fusion System, Medtronic Reusable Instruments for Use with the IPC(TM) Powerease(TM) System, and Medtronic Navigated Manual Reusable Instruments for use with the StealthStation(TM) and IPC(TM) Powerease(TM) Systems

Aug 12, 2016
106 days to decision

K161210 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k161210/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Apr 28, 2016
Decision date	Aug 12, 2016
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek
Location	Memphis, TN, US
Contact	Ankit K. Shah
510(k) history	154 submissions · 147 cleared · 2002-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161210/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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