FDA 510(k) Premarket Notification

K182919 SI-Restore® Sacroiliac Joint Fixation System

CLEARED

Jan 25, 2019
98 days to decision

K182919 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k182919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Oct 19, 2018
Decision date	Jan 25, 2019
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biofusion Medical**
Location	Austin, TX, US
Contact	Rylan Reed
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Surgop Support**
Contact	Daniel Lanois

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182919/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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