FDA 510(k) Premarket Notification

CLEARED

K220888 MySpine S2-SI Pedicle and Sacro-Iliac Screw Placement Guides

May 24, 2022
57 days to decision

K220888 · Product code: **QSR** · Orthopedic
Source: https://www.510kdatabase.net/k220888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Screw Placement Guide (QSR)
Date received	Mar 28, 2022
Decision date	May 24, 2022
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medacta International S.A.**
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026

REGULATORY CONSULTANT

Consulting firm	**Medacta USA**
Contact	Chris Lussier

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