

K200792 MySpine S2-Alar/Alar-Iliac Pedicle Screw Placement Guides

Oct 5, 2020
193 days to decisionK200792 · Product code: **PQC** · Orthopedic
Source: <https://www.510kdatabase.net/k200792/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pedicle Screw Placement Guide (PQC)
Date received	Mar 26, 2020
Decision date	Oct 5, 2020
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medacta Inernational SA
Location	Castel San Pietro (Ch), CH
Contact	Stefano Baj
510(k) history	4 submissions · 4 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200792/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026