

K242603 MyPAO SA guidesNov 19, 2025
446 days to decisionK242603 · Product code: **PBF** · Orthopedic
Source: <https://www.510kdatabase.net/k242603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Aug 30, 2024
Decision date	Nov 19, 2025
Days to decision	446 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	Baj Stefano
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026

REGULATORY CONSULTANT

Consulting firm	Medacta USA
Contact	Christopher Lussier

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242603/> 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 14, 2026