

K220706 MyPAO GuidesMay 30, 2023
446 days to decisionK220706 · Product code: **PBF** · Orthopedic
Source: <https://www.510kdatabase.net/k220706/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopaedic Surgical Planning And Instrument Guides (PBF) |
| Date received | Mar 10, 2022 |
| Decision date | May 30, 2023 |
| 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 | 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](https://accessdata.fda.gov)

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