

K211435 PAO Cortical ScrewAug 6, 2021
88 days to decisionK211435 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k211435/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | May 10, 2021 |
| Decision date | Aug 6, 2021 |
| Days to decision | 88 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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