

K231515 MySpine Cervical GuidesDec 7, 2023
196 days to decisionK231515 · Product code: **QSD** · Orthopedic
Source: <https://www.510kdatabase.net/k231515/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Posterior Cervical Screw Placement Guide (QSD) |
| Date received | May 25, 2023 |
| Decision date | Dec 7, 2023 |
| Days to decision | 196 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 | Lussier Christopher |

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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