

K243610 APTUS Hand SystemMar 7, 2025
105 days to decisionK243610 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k243610/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Nov 22, 2024 |
| Decision date | Mar 7, 2025 |
| Days to decision | 105 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | APTUS Elbow Dorsal Olecranon |

APPLICANT

| | |
|----------------|---|
| Company | Medartis AG |
| Location | San Diego, CA, US |
| Contact | Zurbuchen-De Santis Claudia |
| 510(k) history | 41 submissions · 41 cleared · 1999-2026 |

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