

**K233992 Precision AI Surgical Planning System (PAI-SPS)**Aug 5, 2024  
231 days to decisionK233992 · Product code: **QHE** · Orthopedic  
Source: <https://www.510kdatabase.net/k233992/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Shoulder Arthroplasty Implantation System (QHE) |
| Date received         | Dec 18, 2023                                    |
| Decision date         | Aug 5, 2024                                     |
| Days to decision      | 231 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Precision AI Pty, Ltd.</b>         |
| Location       | Fortitude Valley, AU                  |
| Contact        | Sara Baniadam                         |
| 510(k) history | 3 submissions · 3 cleared · 2024-2026 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233992/> 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 13, 2026