

**K231496 TITAN 3-D Wedge System**Aug 22, 2023  
90 days to decisionK231496 · Product code: **PLF** · Orthopedic  
Source: <https://www.510kdatabase.net/k231496/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Bone Wedge (PLF)                   |
| Date received         | May 24, 2023                       |
| Decision date         | Aug 22, 2023                       |
| Days to decision      | 90 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Paragon 28, Inc.</b>                                   |
| Location       | Englewood, CO, US   |
| Contact        | Haylie Hertz  |
| Website        | <a href="https://paragon28.com">https://paragon28.com</a> |
| 510(k) history | 50 submissions · 50 cleared · 2017-2026                   |

Paragon 28, Inc. is a foot and ankle surgical device company based in Englewood, US. Established in 2010, the company specializes in innovative solutions for foot and ankle procedures. Paragon 28 has received FDA 510(k) clearances from total submissions since 2017. The company's portfolio is entirely focused on Orthopedic devices. Recent clearances include plating systems, nail systems, external fixation devices, and total ankle replacement systems. The latest FDA 510(k) clearance was in 2026, reflecting active ongoing regulatory engagement. The company's product range en...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k231496/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026