

**K250641 APEX 3D Total Ankle Replacement System**May 1, 2025  
58 days to decisionK250641 · Product code: **HSN** · Orthopedic  
Source: <https://www.510kdatabase.net/k250641/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                 |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN) |
| Date received         | Mar 4, 2025  |
| Decision date         | May 1, 2025  |
| Days to decision      | 58 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Paragon 28, Inc.</b>                                   |
| Location       | Englewood, CO, US   |
| Contact        | Edward Wells-Spicer                                       |
| 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...