

**K191782 TTC Phantom Intramedullary Nail System**Sep 6, 2019  
66 days to decisionK191782 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k191782/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Special   |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received         | Jul 2, 2019   |
| Decision date         | Sep 6, 2019   |
| Days to decision      | 66 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Paragon 28, Inc.</b>                                   |
| Location       | Englewood, CO, US   |
| Contact        | Eric Lintula  |
| 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...

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