

## K191227 Paratrooper Plantar Plate Repair System

Jan 24, 2020  
262 days to decisionK191227 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k191227/>

### SUBMISSION DETAILS

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received         | May 7, 2019  |
| Decision date         | Jan 24, 2020   |
| Days to decision      | 262 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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