

**K210390 Apex 3D Total Ankle Replacement System**Mar 6, 2021  
25 days to decisionK210390 · Product code: **HSN** · Orthopedic  
Source: <https://www.510kdatabase.net/k210390/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Feb 9, 2021
Decision date	Mar 6, 2021
Days to decision	25 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	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...