FDA 510(k) Premarket Notification

CLEARED

K223227 MAVEN™ Patient-Specific Instrumentation

Nov 17, 2022
30 days to decision

K223227 · Product code: **HSN** · Orthopedic
Source: https://www.510kdatabase.net/k223227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Oct 18, 2022
Decision date	Nov 17, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Paragon 28, Inc.**
Location	Englewood, CO, US
Contact	Greg Kowalczyk
Website	https://paragon28.com
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...

REGULATORY CONSULTANT

Consulting firm	**Triani Consulting, LLC**
Contact	Jan Triani

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov