FDA 510(k) Premarket Notification

K203385 TenoTac Soft Tissue Fixation System

CLEARED

Feb 11, 2021
85 days to decision

K203385 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k203385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 18, 2020
Decision date	Feb 11, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Paragon 28, Inc.**
Location	Englewood, CO, US
Contact	Haylie Hertz
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...