

K220199 AFFINITY Proximal Tibia SystemMar 21, 2022
56 days to decisionK220199 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k220199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 24, 2022
Decision date	Mar 21, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Techfit Digital Surgery, Inc.
Location	Daytona Beach, FL, US
Contact	Leidy Johanna Toro-Gonzalez
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220199/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026