

K252454 Kinos Total Ankle SystemSep 3, 2025
30 days to decisionK252454 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k252454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Aug 4, 2025
Decision date	Sep 3, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Restor3d
Location	Durham, NC, US
Contact	Brianna Prindle
510(k) history	11 submissions · 11 cleared · 2020-2025

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