

K242868 Kinos Total Ankle SystemOct 18, 2024
28 days to decisionK242868 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k242868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Sep 20, 2024
Decision date	Oct 18, 2024
Days to decision	28 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242868/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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