

K240591 restor3d Kinos Axiom Total Ankle SystemApr 29, 2024
59 days to decisionK240591 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k240591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Mar 1, 2024
Decision date	Apr 29, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Restor3D, Inc.
Location	Durham, NC, US
Contact	Anika Moorjani
510(k) history	6 submissions · 6 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240591/> 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 13, 2026