

**K232595 Kinos Axiom Total Ankle System**Nov 28, 2023  
95 days to decisionK232595 · Product code: **HSN** · Orthopedic  
Source: <https://www.510kdatabase.net/k232595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Aug 25, 2023
Decision date	Nov 28, 2023
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232595/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026