

K201393 restor3d MTP ImplantMay 25, 2022
728 days to decisionK201393 · Product code: **KWD** · Orthopedic
Source: <https://www.510kdatabase.net/k201393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	May 27, 2020
Decision date	May 25, 2022
Days to decision	728 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201393/> 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