

K221220 Montross Extremity Medical Hemi Implant SystemApr 19, 2023
357 days to decisionK221220 · Product code: **KWD** · Orthopedic
Source: <https://www.510kdatabase.net/k221220/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Apr 27, 2022
Decision date	Apr 19, 2023
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Montross Extremity Medical
Location	Colorado Springs, CO, US
Contact	William Montross
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Intrepid Orthopedics, LLC
Contact	Lee Strnad

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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