

K220511 Medline UNITE IM Fibula ImplantMar 22, 2022
28 days to decisionK220511 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k220511/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 22, 2022
Decision date	Mar 22, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, LP
Location	Nortfield, IL, US
Contact	Jennifer Mason
Website	https://www.medline.com
510(k) history	29 submissions · 29 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220511/> 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