

K211944 Medline UNITE® Digital Fusion Screw SystemJul 22, 2021
29 days to decisionK211944 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k211944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 23, 2021
Decision date	Jul 22, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Jennifer Mason
510(k) history	238 submissions · 234 cleared · 1977-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211944/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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