

K210482 Medline UNITE REFLEX Nitinol Staple SystemApr 22, 2021
62 days to decisionK210482 · Product code: **JDR** · Orthopedic
Source: <https://www.510kdatabase.net/k210482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Feb 19, 2021
Decision date	Apr 22, 2021
Days to decision	62 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/k210482/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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