

K243888 Medline UNITE® REFLEX® Hybrid Nitinol Implant SystemApr 11, 2025
114 days to decisionK243888 · Product code: JDR · Orthopedic
Source: <https://www.510kdatabase.net/k243888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Dec 18, 2024
Decision date	Apr 11, 2025
Days to decision	114 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

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