

K211612 Medline UNITE REFLEX Dynamic DiscsDec 10, 2021
198 days to decisionK211612 · Product code: **HTN** · Orthopedic
Source: <https://www.510kdatabase.net/k211612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	May 26, 2021
Decision date	Dec 10, 2021
Days to decision	198 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/k211612/> 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