

K242091 Bolo Button SystemDec 23, 2024
159 days to decisionK242091 · Product code: **HTN** · Orthopedic
Source: <https://www.510kdatabase.net/k242091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Jul 17, 2024
Decision date	Dec 23, 2024
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fusion Orthopedics
Location	Mesa, AZ, US
Contact	Catalina Pardo
510(k) history	2 submissions · 2 cleared · 2022-2024

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