

K150867 Affixus Tibial Nailing SystemJun 10, 2015
70 days to decisionK150867 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k150867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 1, 2015
Decision date	Jun 10, 2015
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	McHenry, IL, US
Contact	SUZANA OTANO
Website	http://www.biomet.com/
510(k) history	440 submissions · 418 cleared · 1978-2024

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...

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