FDA 510(k) Premarket Notification

K021786 TITANIUM ANKLE ARTHRODESIS NAIL

CLEARED

Aug 26, 2002
88 days to decision

K021786 · Product code: **HSB** · Orthopedic
Source: https://www.510kdatabase.net/k021786/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 30, 2002
Decision date	Aug 26, 2002
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	LONNIE WITHAM
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 ...