FDA 510(k) Premarket Notification

CLEARED

K193214 WasherLoc and No-Profile Screw and Washer Systems, Biomet Cannulated Screw System, Biomet Headless Compression and Twist-Off Screws

Nov 10, 2020
355 days to decision

K193214 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k193214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 21, 2019
Decision date	Nov 10, 2020
Days to decision	355 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	Janine Kem
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 ...