

K212431 Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve

Feb 7, 2022
187 days to decisionK212431 · Product code: **JDG** · Orthopedic
Source: <https://www.510kdatabase.net/k212431/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Femoral Component, Cemented, Metal (JDG)
Date received	Aug 4, 2021
Decision date	Feb 7, 2022
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	Gregory Foster
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 ...