

K960363 BIPOLAR SHOULDER PROSTHESIS-SHELL(RD-113130/33, BIANGULAR MODULAR HEAD(RD-113101/41/42, BIOMODULAR MODULAR HEAD(RD-113143

Feb 18, 1997
390 days to decision

K960363 · Product code: **MJT** · Orthopedic
Source: <https://www.510kdatabase.net/k960363/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Humeral (bipolar Hemi-shoulder) Metal/polymer, Cemented Or Uncemented (MJT)
Date received	Jan 25, 1996
Decision date	Feb 18, 1997
Days to decision	390 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	PATRICIA S BERES
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 ...