

K942028 RX90 FEMORAL COMPONENTSep 19, 1994
146 days to decisionK942028 · Product code: **JDG** · Orthopedic
Source: <https://www.510kdatabase.net/k942028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Femoral Component, Cemented, Metal (JDG)
Date received	Apr 26, 1994
Decision date	Sep 19, 1994
Days to decision	146 days
Third-party review	No

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 ...

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