

K974558 SALVAGE/ONCOLOGY HIP AND TOTAL FEMUR SYSTEM

Mar 4, 1998
89 days to decisionK974558 · Product code: JDI · Orthopedic
Source: <https://www.510kdatabase.net/k974558/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Dec 5, 1997
Decision date	Mar 4, 1998
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	PATRICIA SANDBORN 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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Device record: <https://www.510kdatabase.net/k974558/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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