

K853259 MALLORY/HEAD TOTAL HIP SYSTEMNov 1, 1985
91 days to decisionK853259 · Product code: **KMC** · Orthopedic
Source: <https://www.510kdatabase.net/k853259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Composite/metal (KMC)
Date received	Aug 2, 1985
Decision date	Nov 1, 1985
Days to decision	91 days
Third-party review	No

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	JUDITH DERMUDY
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 ...
