FDA 510(k) Premarket Notification

K810258 PROXIMAL FERMORAL HIP REPLACEMENT

CLEARED

Mar 5, 1981
34 days to decision

K810258 · Product code: **JDO** · Orthopedic
Source: https://www.510kdatabase.net/k810258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fixation, Proximal Femoral, Implant (JDO)
Date received	Jan 30, 1981
Decision date	Mar 5, 1981
Days to decision	34 days
Third-party review	No

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
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 ...