FDA 510(k) Premarket Notification

K781389 BIOMET CONCENTRIC HEX SCREW

CLEARED

Aug 21, 1978
11 days to decision

K781389 · Product code: **JDO** · Orthopedic
Source: https://www.510kdatabase.net/k781389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fixation, Proximal Femoral, Implant (JDO)
Date received	Aug 10, 1978
Decision date	Aug 21, 1978
Days to decision	11 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 ...