FDA 510(k) Premarket Notification

K932721 ARTHROTEK SET SCREW

CLEARED

Aug 1, 1994
423 days to decision

K932721 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k932721/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 4, 1993
Decision date	Aug 1, 1994
Days to decision	423 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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k932721/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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