FDA 510(k) Premarket Notification

K780232 RESTRAINT, PROTECTIVE

CLEARED

Feb 21, 1978
12 days to decision

K780232 · Product code: **FMQ** · General Hospital
Source: https://www.510kdatabase.net/k780232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Restraint, Protective (FMQ)
Date received	Feb 9, 1978
Decision date	Feb 21, 1978
Days to decision	12 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Website	http://www.biomet.com/
510(k) history	441 submissions · 419 cleared · 1978-2026

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 ...