

K941245 POLY-MEDICS HEAT PACKMay 2, 1994
48 days to decisionK941245 · Product code: **IMD** · Physical Medicine
Source: <https://www.510kdatabase.net/k941245/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Disposable (IMD)
Date received	Mar 15, 1994
Decision date	May 2, 1994
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	MARY VERSTYNEN
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 ...