FDA 510(k) Premarket Notification

CLEARED

K042093 VANGUARD M SERIES UNICONDYLAR TIBIAL BEARINGS

Nov 1, 2004
90 days to decision

K042093 · Product code: **HRY** · Orthopedic
Source: https://www.510kdatabase.net/k042093/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Aug 3, 2004
Decision date	Nov 1, 2004
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	TAACY BICKEL JOHNSON
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 ...