FDA 510(k) Premarket Notification

K141407 VANGUARD XP FEMORAL COMPONENT(GEN II)/VANGUARD XP FEMORAL TRIAL

CLEARED

Oct 27, 2014
152 days to decision

K141407 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k141407/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	May 28, 2014
Decision date	Oct 27, 2014
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	JULIE GANTENBERG, M.S.
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 ...