

K161592 Persona Partial Knee SystemNov 3, 2016
147 days to decisionK161592 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k161592/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jun 9, 2016
Decision date	Nov 3, 2016
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	Nicole J. Meredith
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 ...