

**K010212 OFFSET TIBIAL TRAY**Feb 14, 2001  
22 days to decisionK010212 · Product code: **MBV** · Orthopedic  
Source: <https://www.510kdatabase.net/k010212/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uhmwpe, Pegged, Cemented, Polymer/metal/polymer (MBV)
Date received	Jan 23, 2001
Decision date	Feb 14, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biomet, Inc.</b>
Location	McHenry, IL, US
Contact	CAROL LAUSTER
Website	<a href="http://www.biomet.com/">http://www.biomet.com/</a>
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 ...