

# K980665 REPICCI II UNICONDYLAR KNEE ALL POLY TIBIAL COMPONENTS

May 20, 1998  
89 days to decisionK980665 · Product code: HRY · Orthopedic  
Source: <https://www.510kdatabase.net/k980665/>

## SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Feb 20, 1998
Decision date	May 20, 1998
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

---

Company	<b>Biomet, Inc.</b>
Location	Mchenry, IL, US
Contact	PATRICIA S BERES
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 ...