

K071107 GENDER SOLUTIONS NATURAL-KNEE FLEX SYSTEMJul 6, 2007
78 days to decisionK071107 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k071107/>**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	Apr 19, 2007
Decision date	Jul 6, 2007
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary
Other names	NEX GEN COMPLETE KNEE SOLUTION CR-FLEX GENDER SOLUTIONS FEMALE FEMORAL COMPON

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	BRANDON HIPSHER
Website	https://www.zimmerbiomet.com
510(k) history	373 submissions · 352 cleared · 1976-2026

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...

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