

**K810520 INSALL/BURSTEIN CONSTRAINED TOTAL CONDYL**Mar 26, 1981  
28 days to decisionK810520 · Product code: **KRO** · Orthopedic  
Source: <https://www.510kdatabase.net/k810520/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Feb 26, 1981
Decision date	Mar 26, 1981
Days to decision	28 days
Third-party review	No

**APPLICANT**

---

Company	<b>Zimmer, Inc.</b>
Location	Warsaw, IN, US
Website	<a href="https://www.zimmerbiomet.com">https://www.zimmerbiomet.com</a>
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 ...