FDA 510(k) Premarket Notification

K760002 KNEE AID

CLEARED

Jul 26, 1976
61 days to decision

K760002 · Product code: **IQI** · Physical Medicine
Source: https://www.510kdatabase.net/k760002/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Limb Brace (IQI)
Date received	May 26, 1976
Decision date	Jul 26, 1976
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Website	https://www.zimmerbiomet.com
510(k) history	374 submissions · 353 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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k760002/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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