FDA 510(k) Premarket Notification

K802676 ORHTOPEDIC REAMER 87 HTD

CLEARED

Nov 12, 1980
14 days to decision

K802676 · Product code: **HTD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k802676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Forceps (HTD)
Date received	Oct 29, 1980
Decision date	Nov 12, 1980
Days to decision	14 days
Third-party review	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 ...