

K053226 ZIMMER AMBULATORY PUMP PAIN MANAGEMENT SYSTEMS WITH FENESTRATED CATHETER AND FLOW SPLITTERJan 31, 2006
75 days to decisionK053226 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k053226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Nov 17, 2005
Decision date	Jan 31, 2006
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	CINDY J DICKEY
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 ...
