CLEARED

Mar 17, 2020
55 days to decision

K200151 Persona Partial Knee Tibial Cut Guide 5 Deg Left Medial Right Lateral, Persona Partial Knee Tibial Cut Guide 5 Deg Right Medial Left Lateral, Persona Partial Knee 2MM Tibial Recutter Left Medial Right Lateral, Persona Partial Knee 2MM Tibial Recutter Right Medial Left Lateral, Persona Partial Knee Tibial Drill

K200151 · Product code: **HSX** · Orthopedic
Source: https://www.510kdatabase.net/k200151/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jan 22, 2020
Decision date	Mar 17, 2020
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	Pankti Shah
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 ...