

K033272 DEPUY SIGMA TIBIAL INSERTSFeb 5, 2004
118 days to decisionK033272 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k033272/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 10, 2003
Decision date	Feb 5, 2004
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DePuy Orthopaedics, Inc.
Location	Warsaw, IN, US
Contact	CHERYL K HASTINGS
510(k) history	206 submissions · 204 cleared · 1998-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033272/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026