

**K963255 PROFIX PLUS TIBIAL INSERT, PROFIX PS PLUS
TIBIAL INSERT, PROFIX P/S TIBIAL INSERT**Jan 2, 1997
136 days to decisionK963255 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k963255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 19, 1996
Decision date	Jan 2, 1997
Days to decision	136 days
Third-party review	No

APPLICANT

Company	Smith & Nephew, Inc., Orthopaedic Div.
Location	Memphis, TN, US
Contact	THOMAS L CRAIG
510(k) history	10 submissions · 8 cleared · 1996-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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