FDA 510(k) Premarket Notification

K963255 PROFIX PLUS TIBIAL INSERT, PROFIX PS PLUS TIBIAL INSERT, PROFIX P/S TIBIAL INSERT

CLEARED

Jan 2, 1997
136 days to decision

K963255 · 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