K011904 NEXGEN PRIMARY POROUS PATELLA, MODEL 04-21 1-IIII-5878-65-ZZ-(STANDARD),04-212-IIII-5878-61-ZZ-(MICRO)

CLEARED

Jul 19, 2001
30 days to decision

K011904 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k011904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 19, 2001
Decision date	Jul 19, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Implex Corp.**
Location	Allendale, NJ, US
Contact	ROBERT A POGGIE
510(k) history	65 submissions · 61 cleared · 1993-2005