K012866 THE NEXGEN TMT TIBIA, MODELS 00-5886-XXYY, 05-120-XXYY-0

CLEARED

Sep 26, 2001
30 days to decision

K012866 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k012866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 27, 2001
Decision date	Sep 26, 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