FDA 510(k) Premarket Notification

K011810 ORTHOGENESIS LPS PROXIMAL TIBIAL REPLACEMENT AND ORTHOGENESIS LPS TIBIAL BEARING

CLEARED

Sep 7, 2001
88 days to decision

K011810 · Product code: **KRO** · Orthopedic
Source: https://www.510kdatabase.net/k011810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Jun 11, 2001
Decision date	Sep 7, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy, Inc.**
Location	Mchenry, IL, US
Contact	JANET G JOHNSON
510(k) history	303 submissions · 239 cleared · 1976-2005