FDA 510(k) Premarket Notification

K012172 DURACON PS LIPPED TIBIAL INSERT

CLEARED

Oct 10, 2001
90 days to decision

K012172 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k012172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 12, 2001
Decision date	Oct 10, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Howmedica Osteonics**
Location	Allendale,, NJ, US
Contact	MARY-CATHERINE DILLON
510(k) history	13 submissions · 13 cleared · 2001-2012