FDA 510(k) Premarket Notification

K063211 PROVEN KNEE SYSTEM HIGH FLEXION TIBIAL INSERT

CLEARED

Jan 18, 2007
87 days to decision

K063211 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k063211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 23, 2006
Decision date	Jan 18, 2007
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stelkast Company**
Location	Pittsburgh, PA, US
Contact	DAVID J STUMPO
510(k) history	40 submissions · 37 cleared · 1994-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k063211/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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