FDA 510(k) Premarket Notification

K101994 APEX KNEE MODULAR TIBIA SYSTEM

CLEARED

Sep 28, 2010
75 days to decision

K101994 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k101994/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 15, 2010
Decision date	Sep 28, 2010
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omnlife Science**
Location	Raynham, MA, US
Contact	RADHIKA TAUNTON
510(k) history	6 submissions · 6 cleared · 2008-2015