K094017 TIBIAL BASEPLATE AUGMENT MODEL KC-22118, KC-22128, KC-22138, KC-22148, KC-22158

CLEARED

Mar 5, 2010
66 days to decision

K094017 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k094017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 29, 2009
Decision date	Mar 5, 2010
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omni Life Science, Inc.**
Location	Raynham, MA, US
Contact	Robert Zoletti
510(k) history	21 submissions · 21 cleared · 2006-2019