FDA 510(k) Premarket Notification

K163332 Apex Revision Knee System

CLEARED

Apr 26, 2017
149 days to decision

K163332 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k163332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 28, 2016
Decision date	Apr 26, 2017
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omnilife Science**
Location	Raynham, MA, US
Contact	Christina Rovaldi
510(k) history	7 submissions · 7 cleared · 2007-2021