FDA 510(k) Premarket Notification

K161414 Anatomic Total Knee System

CLEARED

Jan 19, 2017
241 days to decision

K161414 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k161414/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	May 23, 2016
Decision date	Jan 19, 2017
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Amplitude**
Location	Valence, FR
Contact	MIREILLE LEMERY
510(k) history	2 submissions · 2 cleared · 2017-2023