FDA 510(k) Premarket Notification

K181280 Patello-Femoral Wave (Kahuna) Arthroplasty System

CLEARED

Jun 14, 2018
30 days to decision

K181280 · Product code: **KRR** · Orthopedic
Source: https://www.510kdatabase.net/k181280/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patello/femoral, Semi-constrained, Cemented, Metal/polymer (KRR)
Date received	May 15, 2018
Decision date	Jun 14, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrosurface, Inc.**
Location	Stoughton, MA, US
Contact	Dawn J. Wilson
510(k) history	26 submissions · 26 cleared · 2004-2021