CLEARED

Mar 1, 2017
222 days to decision

K162026 EVOLUTION Revision Tibial Base, EVOLUTION Revision Tibial Block Augment, EVOLUTION Revision Modular Keels, EVOLUTION Revision Stem Adapters (offset and extension), EVOLUTION Revision Cemented Stem Extensions, Canal Filling Stem Extensions

K162026 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k162026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 22, 2016
Decision date	Mar 1, 2017
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Microport Orthopedics, Inc.**
Location	Arlington, TN, US
Contact	Byron Ledbetter
510(k) history	37 submissions · 37 cleared · 2014-2025