FDA 510(k) Premarket Notification

K171389 EVOLUTION Revision CCK System

CLEARED

Aug 8, 2017
89 days to decision

K171389 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k171389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	May 11, 2017
Decision date	Aug 8, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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