

K190355 Precision Casting Solutions Total Knee System

May 16, 2019
90 days to decision

K190355 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k190355/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 15, 2019
Decision date	May 16, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Casting Solutions, Inc.
Location	Oregon City, OR, US
Contact	Jim Moore
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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