

K213389 Identity Imprint Cruciate Retaining (CR) Knee Replacement System and Identity Imprint Posterior Stabilized (PS) Knee Replacement System

Nov 10, 2021
26 days to decision

K213389 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k213389/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 15, 2021
Decision date	Nov 10, 2021
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Conformis, Inc.
Location	Foster City, CA, US
Contact	Kara Johnson
510(k) history	60 submissions · 60 cleared · 2005-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k213389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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