

K212411 Identity Imprint Knee Replacement System (including Identity Imprint Posterior Stabilized (PS) KRS and Identity Imprint Cruciate Retaining (CR) KRS)Sep 23, 2021
51 days to decisionK212411 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k212411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 3, 2021
Decision date	Sep 23, 2021
Days to decision	51 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.netDevice record: <https://www.510kdatabase.net/k212411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026