

K193105 iUni Unicondylar Knee Replacement System, iDuo Bicompartamental Knee Repair System, iTotat CR Knee Replacement System, iTotat PS Knee Replacement SystemMar 13, 2020
126 days to decisionK193105 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k193105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 8, 2019
Decision date	Mar 13, 2020
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193105/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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