

K221404 Identity Imprint Knee Replacement System (including Identity Imprint Posterior Stabilized (PS) KRS and Identity Imprint Cruciate Retaining (CR) KRS)

Jul 26, 2022
71 days to decision

K221404 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k221404/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | May 16, 2022 |
| Decision date | Jul 26, 2022 |
| Days to decision | 71 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k221404/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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