

K231178 ACTERA™ hip systemMay 23, 2023
27 days to decisionK231178 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k231178/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH) |
| Date received | Apr 26, 2023 |
| Decision date | May 23, 2023 |
| Days to decision | 27 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.netDevice record: <https://www.510kdatabase.net/k231178/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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