

**K221104 Actera™ hip system**Aug 4, 2022  
112 days to decisionK221104 · Product code: **MEH** · Orthopedic  
Source: <https://www.510kdatabase.net/k221104/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Apr 14, 2022
Decision date	Aug 4, 2022
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221104/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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