FDA 510(k) Premarket Notification

K221104 Actera™ hip system

CLEARED

Aug 4, 2022
112 days to decision

K221104 · Product code: **MEH** · Orthopedic
Source: https://www.510kdatabase.net/k221104/

SUBMISSION DETAILS

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

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