

**K111916 CONFORMIS IUNI UNICONDYLAR KNEE
REPLACEMENT SYSTEM**Sep 29, 2011
85 days to decisionK111916 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k111916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jul 6, 2011
Decision date	Sep 29, 2011
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111916/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026