

K094013 HLS KNEETEC SYSTEMMay 5, 2011
492 days to decisionK094013 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k094013/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 29, 2009
Decision date	May 5, 2011
Days to decision	492 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tornier
Location	Concord, CA, US
Contact	SEVERINE BONNETON
510(k) history	44 submissions · 44 cleared · 1995-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k094013/> 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 14, 2026