

K143635 KINETIS Total Knee SystemFeb 20, 2015
60 days to decisionK143635 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k143635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 22, 2014
Decision date	Feb 20, 2015
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mako Surgical
Location	Fort Lauderdale, FL, US
Contact	JONATHAN REEVES
Website	http://www.makosurgical.com/
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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