

K180493 A3 Total Knee SystemJun 22, 2018
116 days to decisionK180493 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k180493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 26, 2018
Decision date	Jun 22, 2018
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beijing AK Medical Co., Ltd.
Location	Beijing, CN
Contact	Aiguo Liu
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180493/> 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 16, 2026