

K181146 ASK SystemAug 3, 2018
94 days to decisionK181146 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k181146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	May 1, 2018
Decision date	Aug 3, 2018
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	L and K Biomed Corporation Limited
Location	Yangcheon-Gu, KR
Contact	Semi Jang
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181146/> 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