

K031901 PROVEN REVISION FEMORAL AND PROVEN REVISION TIBIAL INSERTOct 10, 2003
112 days to decisionK031901 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k031901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 20, 2003
Decision date	Oct 10, 2003
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Stelkast Company
Location	Pittsburgh, PA, US
Contact	DONALD A STEVENS
510(k) history	40 submissions · 37 cleared · 1994-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031901/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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