

**K122883 EXP TIBIAL INSERTS AND PATELLAR COMPONENTS
FOR THE PROVEN GEN-FLEX TOTAL KNEE SYSTEM**Aug 5, 2013
319 days to decisionK122883 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k122883/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 20, 2012
Decision date	Aug 5, 2013
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122883/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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