

**K173875 GENFlex2 Total Knee System - Ultra-Congruent CR
Tibial Insert**Jan 19, 2018
29 days to decisionK173875 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k173875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 21, 2017
Decision date	Jan 19, 2018
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stelkast, Inc.
Location	Mcmurray, PA, US
Contact	Dave Stumpo
510(k) history	3 submissions · 3 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Musculoskeletal Clinical Regulatory Advisors
Contact	Hollace Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173875/> 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 June 28, 2026