

K162222 GENflex2 Total Knee System

Sep 7, 2016
30 days to decision

K162222 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k162222/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Aug 8, 2016 |
| Decision date | Sep 7, 2016 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162222/> 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