

**K173455 SurgTech Bipolar Head System**Jun 14, 2018  
219 days to decisionK173455 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k173455/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Nov 7, 2017
Decision date	Jun 14, 2018
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Surgtech, Inc.</b>
Location	Westlake, OH, US
Contact	Xuegong Yu
510(k) history	6 submissions · 6 cleared · 2016-2019

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Orchid Design</b>
Contact	Kellen Hills

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173455/> 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