FDA 510(k) Premarket Notification

K173455 SurgTech Bipolar Head System

CLEARED

Jun 14, 2018
219 days to decision

K173455 · 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	**Surgtech, Inc.**
Location	Westlake, OH, US
Contact	Xuegong Yu
510(k) history	6 submissions · 6 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	**Orchid Design**
Contact	Kellen Hills

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