FDA 510(k) Premarket Notification

K191297 iNSitu Bipolar Hip System

CLEARED

Sep 17, 2019
126 days to decision

K191297 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k191297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	May 14, 2019
Decision date	Sep 17, 2019
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Theken Companies, LLC**
Location	Akron, OH, US
Contact	Garrett Spurgeon
510(k) history	4 submissions · 4 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	**Biovera**
Contact	Bob Poggie

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