

K231905 Electro-Spec Steri-CapsAug 14, 2023
46 days to decisionK231905 · Product code: **HTY** · Orthopedic
Source: <https://www.510kdatabase.net/k231905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Jun 29, 2023
Decision date	Aug 14, 2023
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Electro-Spec, Inc.
Location	Franklin, IN, US
Contact	Jeff Smith
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Kapstone Medical
Contact	Guthrie Carolyn

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

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