

**K150525 SPIES 3D Tip Cam, Image 1 SPIES CCU Image
Connect, Image 1 SPIES CCU D-3 Link**

Nov 20, 2015
263 days to decision

K150525 · Product code: HET · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k150525/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Mar 2, 2015
Decision date	Nov 20, 2015
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	SUSIE S. CHEN
510(k) history	361 submissions · 361 cleared · 1980-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150525/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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