

**K213194 HD Mediastinoscope**Jun 23, 2022  
267 days to decisionK213194 · Product code: **EWY** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k213194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mediastinoscope, Surgical (EWY)
Date received	Sep 29, 2021
Decision date	Jun 23, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KARL STORZ Endoscopy-America, Inc.</b>
Location	Mchenry, IL, US
Contact	Alita McElroy
510(k) history	361 submissions · 361 cleared · 1980-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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