

**K201399 HOPKINS ICG/NIR 10mm Ridgid Endoscope (modified)  
0°, 30°, 45°, HOPKIN ICG/NIR 5mm Ridgid Endoscope (modified)  
0°, 30°, 45°, HOPKIN ICG/NIR 4mm Ridgid Endoscope 0°, 30°,  
45°, VITOM II ICG/NIR Telescope, Power LED Rubina Light  
Source, Foot Switch, Fiber Optic Light Cable, Image S CCU,  
Image S 4U Rubina Camera Head**

Aug 17, 2020  
81 days to decision

K201399 · Product code: **OWN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k201399/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	May 28, 2020
Decision date	Aug 17, 2020
Days to decision	81 days
Third-party review	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/k201399/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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