

K212695 KARL STORZ ICG Imaging SystemNov 15, 2021
82 days to decisionK212695 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Aug 25, 2021
Decision date	Nov 15, 2021
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Karl Storz Endoscopy America
Location	Los Angeles, CA, US
Contact	Mario Trujillo
510(k) history	5 submissions · 5 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212695/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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