

K254242 KARL STORZ ICG Imaging System with RUBINA® Lens

Feb 26, 2026
59 days to decisionK254242 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k254242/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 29, 2025
Decision date	Feb 26, 2026
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Karl Storz SE & CO. KG
Location	Tuttlingen, DE
Contact	Jordan Lydia Verla
Website	https://www.karlstorz.com
510(k) history	23 submissions · 23 cleared · 2018-2026

Karl Storz SE & CO. KG is a medical device manufacturer headquartered in Tuttlingen, Germany. The company specializes in endoscopic instruments and visualization systems for surgical and diagnostic procedures. The company has received FDA 510(k) clearances from total submissions since 2018. Karl Storz devices span multiple surgical specialties, with particular strength in Gastroenterology & Urology applications. The latest FDA 510(k) clearance was granted in 2026, confirming the company's active regulatory engagement. Recent cleared devices include flexible video endoscop...