

K221591 Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope), NIR FI Light SourceFeb 23, 2023
266 days to decisionK221591 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k221591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jun 2, 2022
Decision date	Feb 23, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Schoelly Fiberoptic GmbH
Location	Ayer, MA, US
Contact	Sandra Baumann
510(k) history	12 submissions · 12 cleared · 1999-2024

REGULATORY CONSULTANT

Consulting firm	Delphi Medical Device Consulting, Inc.
Contact	Pamela Papineau

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026