

K233225 SCHOELLY Oxygen Saturation Imaging (OSI) Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope)Jun 20, 2024
266 days to decisionK233225 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k233225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 28, 2023
Decision date	Jun 20, 2024
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)

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