

K231622 REGER Nebulizer Irrigation CannulaSep 29, 2023
119 days to decisionK231622 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jun 2, 2023
Decision date	Sep 29, 2023
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reger Medizintechnik, GmbH
Location	Villingendorf, DE
Contact	Christopher Kohn
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	QSR Consulting
Contact	Kenneth Kleinhenz

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/k231622/> 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