

K242927 Suction Irrigation Tubing SetNov 22, 2024
59 days to decisionK242927 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242927/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 24, 2024
Decision date	Nov 22, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advamedix, GmbH
Location	Karlsruhe, DE
Contact	Dr. Islam Abed
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Traxn Consulting, LLC
Contact	Marianne Jacklyn

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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