

**K233425 FlexTip Bipolar electrodes single-use (AR-S9805-0028), FlexTip Bipolar electrodes single-use (AR-S9805-0035)**Jan 25, 2024  
106 days to decisionK233425 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k233425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 11, 2023
Decision date	Jan 25, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sutter Medizintechnik GmbH</b>
Location	Emmendingen, DE
Contact	Simone Peschl
510(k) history	9 submissions · 9 cleared · 2008-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Visamed GmbH</b>
Contact	Arne Briest

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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