

**K193591 ARC 400**Apr 2, 2020  
101 days to decisionK193591 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 23, 2019
Decision date	Apr 2, 2020
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bowa-Electronics GmbH &amp; Co. KG</b>
Location	Gomaringen, DE
Contact	Wolf-Ruediger Fritz
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Roxana Cernescu

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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