FDA 510(k) Premarket Notification

K193591 ARC 400

CLEARED

Apr 2, 2020
101 days to decision

K193591 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k193591/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Roxana Cernescu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov