

K213386 Titan Manufacturing Bipolar ForcepsOct 25, 2021
12 days to decisionK213386 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 13, 2021
Decision date	Oct 25, 2021
Days to decision	12 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Titan Manufacturing, Inc.
Location	Malvern, PA, US
Contact	Donald Seavey
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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