

**K232992 10THERMA**Dec 20, 2023  
89 days to decisionK232992 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232992/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 22, 2023
Decision date	Dec 20, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tentech, Inc.</b>
Location	Seoul, KR
Contact	Dongok Han
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bt Solutions, Inc.</b>
Contact	Do Hyun Kim

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

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