FDA 510(k) Premarket Notification

K232992 10THERMA

CLEARED

Dec 20, 2023
89 days to decision

K232992 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232992/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Bt Solutions, Inc.**
Contact	Do Hyun Kim

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