

K013034 MODIFICATION TO: THERMACOOL IIAOct 4, 2001
24 days to decisionK013034 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k013034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 10, 2001
Decision date	Oct 4, 2001
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermage, Inc.
Location	Hayward, CA, US
Contact	PAMELA M BUCKMAN
510(k) history	18 submissions · 18 cleared · 2000-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013034/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026