

K053365 MODIFICATION TO THERMAGE THERMACOOL SYSTEM

Dec 13, 2005
11 days to decision

K053365 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k053365/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 2, 2005
Decision date	Dec 13, 2005
Days to decision	11 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

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Device record: <https://www.510kdatabase.net/k053365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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