

K182365 TempSure SystemOct 24, 2018
55 days to decisionK182365 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 30, 2018
Decision date	Oct 24, 2018
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cynosure, Inc.
Location	Bedford, MA, US
Contact	Amy Tannenbaum
510(k) history	98 submissions · 98 cleared · 1992-2019

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