

**K003190 EN BLOC BIOPSY SYSTEM**Jun 11, 2001  
243 days to decisionK003190 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k003190/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 11, 2000
Decision date	Jun 11, 2001
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neothermia Corp.</b>
Location	Natick, MA, US
Contact	SHERRIE COVAL-GOLDMSITH
510(k) history	7 submissions · 7 cleared · 2001-2004

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