

**K031846 CARDIOVATIONS OPTICAL BIPOLAR DEVICE**Jul 21, 2003  
35 days to decisionK031846 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k031846/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 16, 2003
Decision date	Jul 21, 2003
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ethicon, Inc.</b>
Location	Raritan, NJ, US
Contact	PETER CECCHINI
Website	<a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a>
510(k) history	204 submissions · 197 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...

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