

**K944414 DEKALB**Sep 27, 1994  
19 days to decisionK944414 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k944414/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 8, 1994
Decision date	Sep 27, 1994
Days to decision	19 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Endotec, Inc.</b>
Location	South Orange, NJ, US
Contact	FREDDIE P ANDRIENI
Website	<a href="http://www.endotec.com">http://www.endotec.com</a>
510(k) history	15 submissions · 14 cleared · 1991-2009

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944414/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026