

**K083218 TC ENDO PORT**Mar 6, 2009  
126 days to decisionK083218 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083218/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Oct 31, 2008
Decision date	Mar 6, 2009
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Transcardiac Therapeutics, Inc.</b>
Location	Atlanta, GA, US
Contact	DAVID SMITH
510(k) history	1 submissions · 1 cleared · 2009-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083218/> 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 June 23, 2026