

**K970754 INNERDYNE STEP TROCAR EXPANABLE PORT,  
OPEN STEP**

Apr 21, 1997  
49 days to decision

K970754 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k970754/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Mar 3, 1997
Decision date	Apr 21, 1997
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Innerdyne, Inc.</b>
Location	Salt Lake City, UT, US
Contact	RICK GAYKOWSKI
510(k) history	12 submissions · 12 cleared · 1995-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k970754/> Data sourced from FDA 510(k) public records (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. - Generated July 1, 2026