

**K940428 INNERDYNE SINGLE-STICK RADIALY EXPANDING  
DILATOR**Apr 25, 1994  
84 days to decisionK940428 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k940428/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jan 31, 1994
Decision date	Apr 25, 1994
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Innerdyne Medical, Inc.</b>
Location	Mountain View, CA, US
Contact	COLIN J NICHOLS
510(k) history	6 submissions · 5 cleared · 1993-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940428/> 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 6, 2026