

**K955801 RADIFOCUS GLIDEWIRE GT WITH GOLD  
COIL, GLIDEWIRE GOLD**Feb 2, 1996  
42 days to decisionK955801 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k955801/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 22, 1995
Decision date	Feb 2, 1996
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Terumo Medical Corp.</b>
Location	Elkton, MD, US
Contact	KEITH M SMITH
510(k) history	143 submissions · 143 cleared · 1980-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955801/> 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 May 27, 2026