

**K980977 PIOLAX HYDROPHILIC GUIDEWIRE**Oct 27, 1998  
225 days to decisionK980977 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k980977/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 16, 1998
Decision date	Oct 27, 1998
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Piolax Medical Devices, Inc.</b>
Location	Washington, DC, US
Contact	ELIZABETH BIERMAN
510(k) history	1 submissions · 1 cleared · 1998-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980977/> 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 22, 2026