

**K050073 MODIFICATION TO AMPHIRION DEEP 0.014 OTW PTA  
BALLOON CATHETER**Feb 11, 2005  
30 days to decisionK050073 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k050073/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 12, 2005
Decision date	Feb 11, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Invatec Innovative Technologies, S.R.L.</b>
Location	Plymouth, MN, US
Contact	MIKE WINEGAR
510(k) history	7 submissions · 7 cleared · 2005-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050073/>; 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